103

BREAST CANCER IN NORTHEAST OHIO

Y 4. EN 2/3: 103-140

Breast Cancer in Northeast Ohio, Se...

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

AUGUST 1, 1994

Serial No. 103–140

Printed for the use of the Committee on Energy and Commerce

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CONTENTS

Page

Testimony of:

- Chilcote, Nancy, National Breast Cancer Coalition 64
- de Freitas, Gabriel, surgical oncologist, St. Joseph Hospital and Health Center 101
- Duckworth, Leah J., Lorain, Ohio 11
- Johnson, Gabrielle C., Geauga Hospital, Chardon, Ohio 18
- Laing, Glynis, program manager for cancer services, St. Joseph's Hospital and Health Center 73
- McGreer, Barbara Schade, Brunswick, Ohio 4
- Obrams, Iris, Chief of Extramural Programs Branch, National Cancer Institute 80
- Piccioni, Ronna, Geauga Hospital, Chardon, Ohio 28
- Schulte, Paul, epidemiologist, Centers for Disease Control and Prevention 109
- Somani, Peter, director, Ohio Department of Health 47
- Sondik, Edward J., Acting Deputy Director, National Cancer Institute 80

Material submitted for the record by:

- Axel, Andrea Vlock: Statement 135
- Cancer Data System, Inc: Statement 137
- Committee for Nuclear Responsibility: Memorandum to Hon. Sherrod Brown 145
- Lorain County Commissioners: Letter dated July 27, 1994, from Mary Jo Vasi to Hon. Sherrod Brown 147
- Medical College of Ohio: Letter from Stephen Leslie to Hon. Sherrod Brown 152
- Mount Sinai School of Medicine: Statement 159
- Pittsburgh, University of: Letter dated July 20, 1994, from Ernest Sternglass to Hon. Sherrod Brown 163
- Sierra Club: Northeast Ohio Nuclear Committee: Statement of Connie Kline 165

BREAST CANCER IN NORTHEAST OHIO

MONDAY, AUGUST 1, 1994

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Lorain, Ohio

The subcommittee met, pursuant to notice, at 9 a.m. in the auditorium, St. Joseph's Hospital, 205 West 20th Street, Lorain, Ohio, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. I want to welcome you to our subcommittee hearing today.

Today's hearing is on breast cancer and the potential causes of this disease, the benefits of its early detection and the need for quality treatment. This is also a hearing about hope, the hope of making real progress in understanding breast cancer, and in turn, the hope of savings thousands of lives.

This is not an arcane issue. Breast cancer will affect almost every American, personally or because of the illness of a loved one or a friend. It is the most frequent cancer in women. One out of every nine American women will develop the disease during her lifetime. And this year alone, over 45,000 Americans will die of it.

For women and their families living in this part of the country, the impact of breast cancer has been particularly severe. Ohio ranks 9th highest among the 50 States for breast cancer mortality. Breast cancer death rates in several northeast areas of the State are higher than the average. And right here in Lorain County, women face the third highest death rate from breast cancer in all of Ohio.

But breast cancer is not a futile issue. While there is much left to learn—particularly about the problem here in Ohio—we do know how to screen for breast cancer, how to detect it, and how to treat it in its early stages. With existing technologies, breast cancer deaths can now be reduced by at least ⅓. But even with such progress, we know we must do better.

At the request of our colleague, Congressman Brown, we have come to Lorain to examine this national epidemic from the Ohio perspective. Congressman Brown has been a real champion in Congress in pressing for more research to find both a cause and a cure for breast cancer and for greater access to mammography and early treatment services. He has brought us here today because, despite all that we have already achieved, Congressman Brown insists, and rightly so, that there is much more work to do.

With this hearing, we will continue our efforts to get that job done. Breast cancer is an issue of awareness, of education, of financing and of will. With these in action today, we can save women's lives tomorrow.

We are going to prepare a transcript—we have a court reporter—of the hearing and so the testimony that people give today will be very valuable for us to have on the record to share will our colleagues. It will help us back up the efforts for legislative action. I am pleased to be here, and I want to call on my colleague, Congressman Brown, who invited me to be here and has been such a champion in this whole area of trying to do more about the area of breast cancer.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. Particular thanks to Chairman Waxman for coming to Lorain, coming to northeast Ohio today. Chairman Waxman has been chairman of the House Energy and Commerce, Health and the Environment Subcommittee for a decade and a half and there is literally no one in Congress, in forming public policy in this country that has done more to fund women's health research, to work on women's health issues. When so few people were doing it, Henry Waxman was doing it many years ago and I think women in this country and all of us are particularly grateful for his efforts. I also want to thank St. Joe's Hospital for hosting this session and offering us the use of the auditorium this morning.

Women of northeast Ohio have many concerns about breast cancer and its incidence in this part of the State. What we already know is that Ohio ranks ninth in the Nation in mortality from breast cancer. Unfortunately, what we do not know is how to prevent its occurrence. We need to know why it occurs in some counties more than in others. Why does it kill women in our community more than in other communities? Where can we turn for help? What are other types of questions that all of us need to be asking ourselves and each other?

Some experts claim that incidence rates of breast cancer are increasing today due to earlier detection efforts and public information. While early detection may explain a small part of the increased incidence nationwide, it probably cannot explain our increased incidence for the past several years. I believe that public awareness and information about breast cancer and the importance of early detection are just not that good.

In fact, in a survey done by the Ohio Department of Health—and I would add that State Representative Kate Walsh is here, who has played a major, major role in encouraging Dr. Somani and the State Health Department to gather the statistics—that we have wanted for years and finally are beginning to have now. In a survey done by the Ohio Department of Health, over 51 percent of women over 40 said they did not receive a mammogram because, quote, "Their physician did not recommend it", and 31 percent said, quote, "They did not know it was necessary." It is clear we must do a better job of alerting women and their doctors about the risk of developing breast cancer and educating them about the steps that they can take today to deal with its deadly consequences.

Beyond advocating early detection, however, we have few concrete answers. Some experts argue that breast cancer may be linked to pesticides, may be linked to electromagnetic fields, or organochlorines, or other substances which are stored in fat cells. Some have proposed theories centered on occupational links or potential pollutants in our air, in our water, in our food. What has spurred my interest and strengthened my resolve to help our mothers, our daughters and our wives defeat this insidious threat, however, is the reality that the answers to prevention and the answers to cure elude us.

What is clear is that women in northeast Ohio are fearful that they are at an increasing risk of developing breast cancer. I hope that our hearing today and the follow up on that hearing will help to identify the specific areas where more research is needed to answer these complex questions, and that will empower Chairman Waxman and me to further the effort to eradicate this disease from our lives.

At the same time, I hope this hearing will help echo the call of public health professionals and cancer experts that early detection, diagnosis and treatment are unfortunately our only recourse today. If nothing else, I hope women will realize the importance of seeking the most up-to-date information from agencies like the Cancer Society, the Komen Foundation and the public health departments throughout northeast Ohio. While we hope the research of tomorrow will tell women how to avoid breast cancer, early detection is the only message available today.

I would add one other thing. At the conclusion of the hearing, there will be forms in the back of the room that we would like people to fill out if they have questions that they would like addressed by our office, to let us know those comments and questions. Also, if anyone wants to submit any written testimony, we will keep the record open and they can do that today or they can do that at some near point in the future, if they would send those on to our office.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Brown. We will take all the additional testimony and put it in the record.

The members of our first panel of witnesses have first-hand experience in the battle against breast cancer. They represent the thousands of women who have survived the disease, and the thousands more who have provided services to breast cancer patients.

Ms. Barbara McGreer is from Brunswick, Ohio; Ms. Leah Duckworth lives right here in Lorain, Ohio. Ms. Ronna Piccioni and Ms. Gay Johnson are nurses associated with Geauga Hospital located in Chardon, Ohio. I would like to ask them to come forward and take seats at the table.

I want to welcome you to our hearing today. We very much appreciate your being here. You have prepared statements in advance of this hearing and those statements will be put in the record in full. We would like to recognize each of you and hope that you will limit your testimony to around 5 minutes so we can hear from all the other witnesses and we can ask questions. I will not cut you off and will not strictly enforce the 5-minute rule, but we would like you to try to limit it to 5 minutes. More importantly, what we want is to hear from you, your own experiences, your own thoughts about what we should do about this problem.

Ms. McGreer, why don't we start with you.

STATEMENTS OF BARBARA SHADE McGREER, BRUNSWICK, OHIO; LEAH J. DUCKWORTH, LORAIN, OHIO; AND GABRIELLE C. JOHNSON, AND RONNA PICCIONI, REGISTERED NURSES, GEAUGA HOSPITAL, CHARDON, OHIO

Ms. McGREER. My name is Barbara Schade McGreer. I live in Brunswick where I am a program supervisor at our new recreation center. I have a husband, two sons, four daughters, a grandson and a granddaughter. I am here today for these young ladies—Moira, Kerry, Katie, Megan and little Laura—and also for your young women who may some day develop breast cancer, or far better yet, may not develop breast cancer because of the thoughts and actions we consider today.

I was 46 in early March 1990, when I noticed a small indentation on my left breast. I did exactly what I was supposed to do—I called the doctor. For the next 8 months, modern medical technology failed me. The cloudy mammogram was read negatively. The physical exam showed only a dent when I lifted my arm. The sonogram failed to show the fluid-filled lump that eventually developed. The needle biopsy gave no evidence of malignant cells.

On October 31, I decided to see a breast specialist, Dr. Laurence Levy, about what I hoped was a persistent cyst. My history of delays, he said, was all too common. But less than 24 hours later, he gave me an accurate diagnosis.

The 2 weeks of frenzy that followed are familiar to breast cancer patients. Lucky us, we get to choose. I had 11 days in which to become a breast cancer expert—a formidable task. Six books and four doctors' opinions later, the data were in.

The tumor was suitable for lumpectomy; it necessitated mastectomy. Radiation treatment caused serious damage; it produced minimal damage. Reconstruction was appropriate immediately; it was safer later. More surgery was better; less surgery was better. I wanted so much to make a good medical decision. My emotions were telling me that the greater my sacrifice, the greater the reward. But the NSABP study showed equal survival rates in situations like mine. Lumpectomy plus radiation was as good as mastectomy. In spite of Dr. Poisson's dishonesty, I believe this remains true today.

Eventually I gave up trying to become an expert and trusted the expertise of Dr. Levy. At that time, my insurance gave me unrestricted freedom of choice of physicians. My current managed care plan requires a referral to a specialist chosen from a restricted list. Such restriction could have impacted my health, since not all doctors are created equal. Dr. Levy removed a small invasive tumor.

By the grace of God, in spite of 8 wasted months, the tumor had not spread to a single one of 26 lymph nodes removed. The tumor had positive hormone receptors. I began taking tamoxifen because an NSABP study showed that women with similar tumors survived longer with tamoxifen treatment. I continue to take tamoxifen in spite of the controversy and the presence of side effects, including recently uterine polyps. With the assistance of a telephone conversation with Dr. Abrams at the National Cancer Institute, I have worked through the fear of uterine cancer, resisting the emotional response, abiding by the intellectual decision, and agreeing with him that the benefits outweigh the risks.

After the surgery, I agreed to participate in a clinical trial to determine the effectiveness of two chemotherapy treatments. This was my opportunity to help other women receive improved treatment as I believe I had benefited from the lumpectomy trial and the tamoxifen trial. Unfortunately, even before the latest controversy, only about 2 percent of cancer patients participate in clinical trials.

During my recovery, I decided to do whatever I could to improve the situation for me and others. I went back to the people who had failed to diagnose my tumor, politely pointing out their errors and admonishing them to learn from their mistakes, particularly the radiologist who could have detected my tumor a week after I saw it, that little dent, if he had been more conscientious in pursuing a definitive reading of a clear mammogram.

So my story is not tragic or unusual. I have a good prognosis. I kept most of my breast. It has feeling. There is only minor pain and swelling. My partially numb arm has full movement. All alarms have been false; all test results good. So what is the big deal? How important are two healthy, functional breasts? It is easier to function without a breast than without a hand, I thought, as I watched a man with a hook for a hand. We can survive without breasts. But should we have to? Is this our legacy to our children—a society of Amazons sacrificing their breasts, not to war, but to disease?

God created women with two breasts. For centuries, women's breasts ensured the survival of their infants. Most men and women acknowledge the significant role of breasts in sexuality. They are not easy things to give up. Yet I have met women willing to cut off both healthy breasts in fear—justified or not—of dying of breast cancer. For my survival, I would part with my breasts.

I have nursed my babies, enjoyed attractiveness and sexual feelings. But that is not good enough for our daughters. I am not content just to tell them to watch for lumps so they can have early surgery. I want them to be able to keep their functioning breasts.

For myself, I can wonder what might I have done wrong—dietary fat, oral contraceptives, exposure to environmental hazards? But that is not good enough for our daughters—having all of the questions and none of the answers. I want to tell them, "If you live a certain way, you can expect to live long with all your sexual organs intact and healthy."

I want desperately to finish raising my children. But I must accept the possibility of a shortened life span. But that is not good enough for our daughters. I want them to live and love and to watch their grandchildren grow up.

I live in the bedroom community of Brunswick. My neighbor, Ben, 37, handsome, vigorous, friendly died a few days before Christmas of a rare bone marrow cancer. You can stand in his widow's yard, take a rock, throw it north, then south, then east, then west, each time striking a woman who has had breast cancer, except that one is dead. I personally know of 3 others within a block or 2 in each direction, 5 of us were under 50, 2 of us were under 40. Is cancer in our water, our soil? Should I move away to protect my daughters?

My youngest daughter is 10 years and 8 months old. Her breasts are developing earlier than her sisters. It makes me want to cry. My imperfect knowledge tells me—too much estrogen, too soon, increased risk of breast cancer for my baby. Is estrogen the culprit? But having estrogen is essential to being a healthy, functioning female. Is it the artificial estrogen found in chemicals that insidiously work their way into our bodies through the food chain, the polluted environment? What can we tell our daughters? How can we find the answers?

Do we care enough about the women of the future to honestly and accurately scrutinize the conditions of the present? Breast cancer research has come under heavy fire, some of it well-deserved, some of it sensationalized or misunderstood. But research is our best tool for improving the future, provided that it is conducted with total scientific integrity and accurate results are reported in a way that is truly understandable to the persons it affects.

Participants in clinical trials must be fully informed, but with sensitivity. We women must be courageous and altruistic enough to assume some of the calculated risks of clinical trials. I have enormous gratitude to the healthy women participating in prevention trials. They are my daughters' best hope.

I want the leaders in politics, medicine and society to have the wisdom to invest in all our daughters' future by keeping breast health a top priority in any discussion of medical care and insurance plans. I want the decision-makers to recognize the benefit of access to highly skilled specialists. I want support for early detection through more, not less, high quality mammograms and universally good examining techniques. I want old research cleaned up without stopping important studies. I want new research into treatment, cause and prevention of breast cancer.

Finally, my advice to all women and to those who care about them—these eyes, these fingers and this persistent spirit is what saved my life. You cannot bury your heads in the sand. What you do not know can kill you.

Mr. WAXMAN. Thank you very much, Ms. McGreer; very, very good testimony.

[The prepared statement of Ms. McGreer follows:]

STATEMENT OF BARBARA SCHADE McGREER

My name is Barbara Schade McGreer. I live in Brunswick where I am a program supervisor at our new Recreation Center. I have a husband, two sons, four daughters, a grandson and a granddaughter. I am here today for these young ladies-- Moira, Kerry, Katie, Megan, and Laura,and for your young women who may someday develop breast cancer, or far better yet, may not develop breast cancer because of the thoughts and actions we consider today.

I was 46 in early March, 1990, when I noticed a small indentation on my left breast. I did exactly what I was supposed to do. I called the doctor. For the next eight months modern medical technology failed me: The cloudy mammogram was read negatively. The physical exam showed only a dent when I lifted my arm. The sonogram failed to show the fluid filled lump that eventually developed. The needle biopsy gave no evidence of malignant cells.

On October 31, I decided to see a breast specialist, Dr. Laurence Levy, about what I hoped was a persistent cyst. He examined my entire chest, not just the round parts,and removed tissue from the lump with a syringe much different from the one used in the first biopsy. My history of delays, he said, was all too common. But less than twenty-four hours later, he gave me an accurate diagnosis.

The two weeks of frenzy that followed are familiar to breast cancer patients. Lucky us. We get to choose. I had eleven days in which to become a breast cancer expert. A formidable task! Six books and four doctors' opinions later the data was in: The tumor was suitable for lumpectomy; it necessitated mastectomy. Radiation treatment caused serious damage; it produced minimal damage. Reconstruction was appropriate immediately; it was safer later. More surgery was better; less surgery was better. I wanted so much to make a good medical decision. My emotions were telling me that the greater my sacrifice, the greater the reward. But the NSABP study showed equal survival rates in situations like mine. Lumpectomy plus radiation was as good as mastectomy. In spite of Dr. Poisson's dishonesty,I believe this remains true today after thorough discussion about the studies with Mt. Sinai Hospital personnel.

Eventually, I gave up trying to become an expert and trusted the expertise of Dr. Levy. At that time my insurance plan gave me unrestricted freedom of choice of physicians. My current managed care plan requires a referral to a specialist chosen from a resticted list. Such restriction could have impacted my health, since not all doctors are created equal. Dr. Levy removed an infiltrating ductal carcinoma, 1.5 cm X 1.2 cm.

By the grace of God, in spite of eight wasted months, the tumor had not spread to a single one of twenty six lymph nodes removed. The tumor had positive hormone receptors. I began taking tamoxifen because a NSABP study showed that women with similar tumors survived longer with tamoxifen treatment. I continue to take tamoxifen in spite of the controversy and the presence of side effects,including recently removed uterine polyps. With the assistance of a telephone conversation with a doctor at the National Cancer Institute, I have worked through the fear of uterine cancer, resisting the emotional response and abiding by the intellectual decision. At my age, I acknowledge the expendability of my uterus and continue to have faith that tamoxifen will starve cancer and perhaps help my heart and bones. The doctor from the National Cancer Institute regrets that his very detailed honesty has frightened some cancer patients about tamoxifen. He believes the benefits outweigh the risks.

After the surgery, I agreed to participate in a clinical trial to determine the effectiveness of two chemotherapy treatments. This was my opportunity to help other women receive improved treatment as I believe I had benefitted from the lumpectomy trial and the tamoxifen trial. (I was disppointed to be randomized to the control group. My emotions told me that more treatment was better treatment, but that won't be known until the research is complete. As Milton said,"They also serve who only stand and wait.") Unfortunately, before the controversy, only a small percentage of breast cancer patients participated in clinical trials.

During my recovery, I decided to do whatever I could to improve the situation for me and others. I went back to the people who had failed to diagnose my tumor, politely pointing out their errors and admonishing them to learn from their mistakes, particularly the radiologist who could have detected my tumor a week after I saw that little dent if he had been more conscientious in pursuing a definitive reading of a clear mammogram. I also tried hard to be positive- to thank people who were good to me, who were doing things right.

So my story is not tragic or unusual. I have a good prognosis. I kept most of my breast; it has feeling. There's only minor pain and swelling. My partially numb arm has full movement. All alarms have been false; all test results good. So what's the big deal? How important are two healthy, functional breasts? It's easier to lose a breast than a hand, I thought, as I watched a man function with a hook for a hand. We can survive without breasts. But should we have to? Is this our legacy to our children? A society of Amazons, sacrificing their breasts not to war but to disease?

God created women with two breasts. For centuries women's breasts insured the survival of their infants. Most men and women acknowledge the significant role of breasts in sexuality. They are not easy things to give up. Yet I have met women willing to cut off both healthy breasts in fear, justified or not, of dying of breast cancer.

For my survival I would part with my breasts. I have nursed my babies, enjoyed attractiveness and sexual feelings.

But that isn't good enough for our daughters. I am not content just to tell them to watch for lumps so they can have early surgery. I want them to be able to keep their functioning breasts.

For myself I can wonder what I might have done wrong- dietary fat? oral contraceptives? exposure to environmental hazards?

But that isn't good enough for our daughters, having only the questions and none of the answers. I want to tell them," If you live a certain way, you can expect to live long with all your sexual organs intact and healthy."

I want desperately to finish raising my children. But I am fifty-one and I must accept the possibility of a shortened lifespan.

But that isn't good enough for our daughters. I want them to live and love and have children of their own.

I live in the bedroom community of Brunswick. You could walk two doors down, throw a rock north, then south, then east, then west, each time striking a woman who has had breast cancer. Except that one is dead. I personally know three others within another block or two in each direction. The lifetime risk to age eighty plus is one in nine. Five of us were under fifty. Two of us were under forty. Is cancer in our water? Our soil? Should I move away to protect my daughters?

My youngest daughter is ten years and eight months old. Her breasts are developing earlier than her sisters. It makes me want to cry. My imperfect knowledge tells me-- too much estrogen--too soon--increased risk of breast cancer for my baby. Is estrogen the culprit? But having estrogen is essential to being a healthy, functioning female. Is it the artificial estrogen found in chemicals that insidiously work their way into our bodies through the food chain, the polluted environment? What can we tell our daughters? How can we find the answers?

Do we care enough about the women of the future to honestly and accurately scrutinize the conditions of the present? Breast cancer research has come under heavy fire, some of it well-deserved, some of it sensationalized or misunderstood. But research is our best tool for improving the future, provided that it is conducted with total scientific integrity; and accurate results are reported in a way that is truly understandable to the persons it affects. (Recently, Mt. Sinai Hospital invited all clinical trial patients to a meeting to explain all the controversy and its impact, and to answer all questions.)

Participants in clinical trials must be fully informed, but with sensitivity. We women must be courageous and altruistic enough to assume some of the calculated risks of clinical trials. I have enormous gratitide to the healthy women participating in prevention trials. They are my daughters' best hope.

We've hit some chuckholes in this road of research--falsified data, small but real risks in tamoxifen treatment, a vote of no confidence for mammograms in women under 50. But those of us who live in Northeastern Ohio know all about chuckholes. You maneuver your way around them, be patient while they're being repaired, and get on to your destination.

I want the decision makers to recognize the benefit of access to highly skilled specialists. I want support for early detection through more, not less, high quality mammograms and universally good examining techniques. I want old research cleaned up without stopping important studies. I want new research into treatment, cause, and prevention of breast cancer.

I hope that the story of my experience with breast cancer has led you to my conclusions:

1. We must maximize the present body of knowledge about breast cancer. Simple circular breast exams must be abandoned in favor of complete vertical breast exams. Old mammography machines must be abandoned in favor of newer, high resolution machines. Mammography must continue to be encouraged in women under fifty. Doctors must keep their knowledge and skills updated through professional seminars. Medical professionals must err on the side of caution in the face of uncertain findings.

2. We must continue research of the highest quality. Research errors should be corrected and accurate results made public in non-sensational ways. The medical profession should provide every affected woman the opportunity to have full explanation about current controversy. Research must continue into better treatment and early detection of breast cancer. However, we must also pursue research into its causes and prevention so that we may pass on to our children the legacy of fully healthy lives.

3. Women must come to see themselves as survivors and victors, not victims. They must become genuine participants in controlling this epidemic. They must be knowledgeable and aggressive in their pursuit of good health and good doctors. They must face their fears and work through their emotions with knowledge and empathy from the medical profession and their own reason. They must be courageous enough to participate in clinical trials to advance research. Healthy women must be altruistic enough to particpate in research about prevention of this disease.

4. Freedom of choice means better health care. In our national effort to make all things equal for all people, let us be wary that it does not become equally diminished quality of care for all.

Mr. WAXMAN. Ms. Duckworth, we are going to hear from you next. And let me ask the audience, if you would refrain from applauding. I know that for a lot of this testimony, you feel you really want to applaud, but I would prefer if you did not because it then leads to people to applaud when they agree and express themselves when they disagree and that is usually not the way we want to conduct this kind of a hearing.

Ms. Duckworth.

STATEMENT OF LEAH J. DUCKWORTH

Ms. DUCKWORTH. Good morning. My name is Leah Duckworth and I am called a breast cancer survivor. I am a wife, a mother and an expectant grandmother—my first grandchild due this December. I have been employed for the past 10 years as the office manager for Dr. Romeo Diaz, in my opinion one of the greatest doctors in the world. And it is wonderful to see all of you here today, and it is most wonderful to see so many of the patients here today that we see in the office every week.

I am here today to tell you my story, and it is not a horror story, as was stated by a reporter in our local paper, which very much upset me. It is not a horror story; it is my journey. It is one woman's journey of a discovery that put me on the path that brought me here to you today. I hope I can be a voice for those who can no longer speak. This is for my daughter Tracy, a very high risk young lady for breast cancer. This is for my best friend Carol, who is going to celebrate her last birthday this Thursday. She is dying of breast cancer. We have been friends for 40 years.

My past history: In December 1979, I found a lump in my right breast. I did what we were told to do, examine your breasts on a monthly basis. I found a lump. Of course, it was right before Christmas, so I put off the breast exam, right? I finally went—had a breast exam and sure enough there is a lump. I had a mammogram. I was directed to Dr. Diaz, which I consider to be one of the best things that ever happened to me. Things went quickly. A biopsy was scheduled. You went to the hospital for 3 days, you were put to sleep, you woke up with part of your breast gone and I woke up to him standing next to me and he said it is malignant and he looked at me and he said, "You are not surprised, are you?" And I said no I was not. I do not know why I was not surprised, but I really did not expect to hear any other diagnosis.

Decisions had to be made. A mastectomy was scheduled for me and an axillary node dissection. It all went off without a hitch. I did very well. Pathology came back with one positive lymph node, which that is good, that was all right. Now we are talking 1980, we are talking 14 years ago. There was no tamoxifen, I do not think, available for me at that time. No chemotherapy was needed, no radiation treatment. I saw the doctor every 3 months after that. I had very close, careful follow-up, regularly scheduled important bone scans, mammograms, chest x rays, blood work. And I was doing very, very well.

I made a wonderful recovery, I had my family—my children were 14 and 18 at the time, and I just, like every woman, wanted to live. I wanted to see my children grow up. I wanted to see them on their own.

After a few years, it looked like that was going to happen, that I was going to be around and I decided I needed to do something else with my life, something important for me.

I enrolled in a medical business school, with my daughter, and I was 44 years old. I went to school full time for 9 months. I did not think I was going to be able to handle the physical rigors of it, but I did, and I learned and I graduated with a 4.0 grade average and I was very proud of myself. And I was able to do on-the-job training with Dr. Diaz and I have been there ever since. I am his office manager.

In 1984, my mother was diagnosed with advanced breast cancer. By the time we had her diagnosis, it had spread to her bones. I was very upset. I was angry with my mother. How could she have felt pain in her bones and felt lumps in her breast and not tell me. She went through it with me; she was supportive and crushed and devastated as only a mother can be with a daughter with breast cancer. But she did not tell me. And I made some choices with her. We got her some good treatment. She had radiation. She had chemotherapy—Dr. Diaz was my mother's doctor. She did very well for about 4 years. I was glad to have those years with her.

In May of 1987, 7 years post-first breast cancer, I had my yearly routine tests—mammogram, bone scan, blood tests, chest x ray. The mammogram came back with what is called a micro-calcification, something that is so tiny, you cannot feel it. It can be seen microscopically. Although Dr. Diaz did not seem too concerned or upset about it, he said let us biopsy this. So this time when I went to the hospital in 1987, it was done as an out-patient and I got on the table, had the surgery and went to lunch.

And the pathology came back and it was malignant. It was as cancerous as the lump that I had felt in the right breast. How could this be? I could not feel this. Do they not tell us to feel for lumps, examine our breasts, look for lumps? This was something so tiny, it would not have been felt as a lump for years. It was microscopic, but it was just as malignant as the lump, which shows the value of mammography. It shows the value of early detection.

Of course, at 7 years later, having worked with our breast cancer patients, I had too much knowledge, and I was terrified and upset and devastated and sure this was going to be the time that I was not going to survive.

We did some surgery—did a lumpectomy and axillary node dissection and the pathology came back exactly the same as the first time, one positive lymph node. I had to make some choices as to what I wanted to do. We put me on tamoxifen, which I have been on for 7 years. And then I elected to have a second mastectomy, which shocked a lot of people—why would you do that? I had had a breast reconstruction the first time and I chose to have a mastectomy the second time and I would have that breast reconstructed to match—which of course, breast implants and breast reconstruction is a whole other story, which we are not going to talk about.

On the day of my surgery for the second breast cancer in May of 1987, my mother was admitted to the hospital for the last time. Our rooms were across from each other. I waved to her as they took me to surgery. I went home but my mother never did. She died at the age of 69, on June 11, 1987. I had been diagnosed at the age of 39. My mother died at 69. My mother's sister died 2 years later. All of us were born and raised in Lorain and many of us delivered here at St. Joseph's Hospital, including my children.

In these 14 years, I have met many women like me. We are every woman. We are your wives, your mothers, your daughters, sisters, granddaughters, aunts, nieces and lovers. We are your best friend, your neighbor, your co-worker. We are young and we are old. We are single and married, divorced and widowed, every race, every ethnic background, every religious affiliation, every sexual orientation and every socio-economic background. We are mothers and we are childless. We are employed in all walks of life. Maybe we are your worst nightmare. If this can happen to us, maybe it can happen to you. When I was diagnosed with breast cancer in 1980, the statistics were, 1 in 17 women might get breast cancer in their lifetime. Today, as you were told earlier, it is 1 in 9.

I have never heard a breast cancer patient say why me. But I have heard why. We want to know why this happened to us. We blame ourselves. Is it something we did? We ate too high a fat diet, took high estrogen birth control pills. Did we have our children too young? Did we have them too late in life? Did we not have them at all? Or is it something we didn't do. Didn't take our vitamins, watch our diets, exercise, go for regular check-ups. Unfortunately in these past 14 years, I have heard very few answers. We read of possible causes, studies are done, no conclusions are reached, research continues.

I find it interesting that once the diagnosis is made, we have wonderful resources, especially in northeast Ohio. We have wonderful health care providers, doctors, surgeons, radiation therapists, chemotherapy nurses. We have support groups for each other. But this is all after the fact, after the fact of diagnosis.

And finally we begin to look outside ourselves for answers. In my neighborhood, within 5 minutes, there are 5 of us. My best friend lives across the street, another lady around the corner, another one down the street, another one half a block away. We are all of the same age, most of us born and raised in Lorain, Ohio and probably most of us delivered here at St. Joe's. We want to know, is it in the air that we breathe, the food that we eat, the water? We want some answers so that maybe there is a way to prevent this from happening to somebody else. So much of what we are able to do is after the fact, after the diagnosis of breast cancer is made.

In my daily work, I have met so many women like me; we have a wonderful common bond. People will come in to the office and they hear voices raised in laughter and conversation and I have had said to me, "Well, I expected this place to be very serious because you are dealing with serious illness." Yes, we are dealing with serious illness. Every one of us in our own way. Laughter helps, and we do laugh together and we do cry together and we support each other in every way that we can. We are a common bond.

It is good for the patients to know that I have had breast cancer and I have a job that I love and I have children and I have a family. But my heart is filled with sorrow for the women who cannot be here any more, including my mother. She will never see her granddaughter, Mary. She will never see her first great grandchild. And my best friend may never see another birthday.

The medical community today has many resources for breast cancer patients. We have many options, many choices. Our tests today that are available give us clear indications of what is needed as far as treatment. The bottom line is it is your choice to make about what kinds of treatment you choose to have, or not to have. We want you to be a partner in all these decision-makings.

In conclusion, I would like to see more research into environmental causes for not only breast cancer but for all the other types of cancers that are on the rise today.

Thank you.

Mr. WAXMAN. Thank you very much, Ms. Duckworth.

[The prepared statement of Ms. Duckworth follows:]

STATEMENT OF LEAH J. DUCKWORTH

I am Leah J. Duckworth, a breast cancer survivor. wife, mother, and an expectant grandmother, with my first grandchild due this December. I have been employed, for the past ten years, as the office manager for Dr. Romeo M. Diaz, our area's leading breast cancer surgeon and specialist.

I'm here today to tell you my story, not a "horror" story as stated by a reporter in our local morning paper, but one woman's journey of a discovery that put me on a path that has led me here to you today. I hope that I can be a voice for those who can no longer speak.

In December, 1979, I found a lump in my right breast. That was 14 years ago. 14 years of fear, anxiety, questions, answers, knowledge, and the opportunity to meet and speak with many other women like me. After the discovery of this breast lump, things happened very quickly. I had a mammogram and then a meeting with Doctor Diaz. A breast biopsy was scheduled. In 1980, you were admitted for this procedure which was done under a general anesthetic with a 3 day hospital stay. How very different from today when this procedure is done with local anesthesia as an out-patient. The pathology report came back and the lump was malignant. I wasn't surprised to hear that I had cancer, but I don't know why I wasn't surprised. I had a modified radical mastectomy. I had one positive lymph node. One month later, I had a bilateral salpingo-oophorectomy, pretty much a standard at that time for estrogen dependent breast cancer. I was immediately sent into surgical menopause, which, for me, was worse than the surgery.

I made a wonderful recovery, mainly due to the love and support of my family and friends. My children were teenagers at the time, and I just wanted to live to see them grown and on their own.

Follow-ups with Doctor Diaz were scheduled for every 3 months. Evaluations consisted of mammograms, chest x-rays, bone scan, and blood tests to see if the cancer was active. All tests were normal. I had a great sense of well-being, but a restlessness filled my life. I wanted to do something meaningful with the rest of my life. The breast cancer, for me, was a wakeup call to get on with my life and maybe do something to help other women like me.

I enrolled in business school with my then 18 year old daughter to become a medical office assistant. I was fearful of going back to school full-time at the age of 44, not because of I felt I couldn't learn, but because I didn't know if I had the physical stamina to do it. I did it and graduated with a 4.0 grade average. I found that I really loved the work and was able to do an externship at Doctor Diaz's office. I was hired on a part-time basis and became the office manager in 1985. I felt that I had found my niche in life. I love every moment of being there, despite all the stress involved with a practice like ours. My days were filled. My family was growing. I was happy, knowing that I could make a difference in other women's lives.

In May, 1984, my mother was diagnosed with advanced breast cancer. Sadly, by the time of her diagnosis, the cancer had already spread to her bones. I was angry with her. How could she not have told me that she lumps in her breasts and pains in her bones? She had been so supportive of me during my illness even though I knew that she devastated as only a mother can be when her daughter has breast cancer. How could she have let this disease get so far? It was her fear and denial that anything was wrong. Sadly, something that we still see today. We did all we could for her within the medical community. She had surgery, chemotherapy and radiation as her treatments. She did fairly well for 4 years.

In May, 1987, I again had my routine evaluation for breast cancer including a mammogram on the left breast. The x-ray report came back showing a microcalcification in the left breast. Doctor Diaz reviewed the mammogram and didn't seem too alarmed with the appearance of this microscopic calcification. A biopsy was scheduled and the pathology report came back as malignant! A second primary! I was devastated. I was then 7 years post-op with the right breast cancer and had never felt better in my life. How could this happen to me again? I had too much knowledge this time around and was really certain that this time I wouldn't survive. After considering all my options, I elected to have a lumpectomy and axillary node dissection. The pathology report showed residual tumor at the lumpectomy margins and again with one positive lymph node. The diagnosis was exactly the same as the right breast cancer 7 years earlier. The right breast cancer had begun with a lump that I could feel with my fingers. Isn't that what they tell us to look for when we do our breast self-examinations? This left breast cancer had begun with something so tiny that you could only see it microscopically. This really showed me the value of mammography for this wouldn't have been felt as a lump for years. A classic example of early detection. My husband and children were devastated with this new breast cancer. My son still has difficulty even talking about it. My daughter was and is, very concerned, loving and supportive, knowing the legacy she may face one day.

On the day of mysurgery for this second breast cancer, my mother was admitted for her final hospital stay. Our rooms were across from each other. I went home, but she never did. She died on June 11, 1987, at the age of 69. I had been diagnosed at the age of 39, my mother died of breast cancer at the age of 69. Her sister, Ann, died of breast cancer 2 years after my mother. We were all born and raised in Lorain, Ohio, many of us delivered here at St. Joseph Hospital & Health Center.

After all of the pathology came back from the lumpectomy and axillary node dissection, I elected to have another mastectomy on the left breast. My choice. My decision. I had had a breast reconstruction on the right side and decided to go that route again. The breast reconstruction, is, of course, another story. I was placed on tamoxifen 7 years ago and continue to take it today. I am alive and well and continuing my work with our breast cancer patients.

In these 14 years, I have met many women like me. We are Everywoman. We are your wives, mothers, daughters, sisters, grandaughters, aunts, neices, lovers. We are your best friend, your neighbor, and your co-worker. We are young and we are old. We are single, married, divorced, and widowed. We come from every race, every ethnic background, every religious affilation, every sexual orientation, and every socio-economic background. We are mothers and we are childless. We are employed in all walks of life. We are doctors, lawyers, teachers, homemakers, nurses, factory workers, secretaries, politicians and entertainers. Maybe we are your worst nightmare. If this can happen to us, maybe it can happen to you. When I was disgnosed with breast cancer in 1980, I was 1 in 17 women who might get breast cancer in her lifetime. Today, it is 1 in 8 women.

I have never heard a breast cancer patient ask "why me?" But I have heard "why?" We want to know why this happened to us. We ask ourselves what we did wrong to cause this disease. Did we take high-estrogen birth control pills when they first came on the market? Did we have a high fat diet? Did we have our children too young? too old? not at all? Is it something that we did not do? We didn't take our vitamins? diet? excersice? have regular check-ups? Unfortunaetely, in these past 14 years, I have heard very few answers. We read of possible causes. Studies are done. No conclusions are reached. Research continues.

Interestingly enough, once a diagnosis of breast cancer is made, the medical community springs into action for us. We can have, or not have, surgery, chemotherapy, hormonal therapy, and radiation therapy. All options that can help us to live longer. We are fortunate to live in this area as we have some of the finest breast cancer care available. We have dedicated health care professionals including doctors, nurses, radiation therapists, oncologists and psychologists.

Finally, we begin to look outside ourselves for answers. Why in my neighborhood, within a few blocks, are 5 women of my age who all have breast cancer? Co-incidence? Why my mother, aunts, and me, all born and raised in Lorain, Ohio, all of us with this disease? What about my daughter? What about my husband's co-workers wives? How many of them have breast cancer? Is it in the air that we breathe? The food that we eat? The water that we drink? We would like some answers, so that maybe there will be a way to prevent this disease from happening to other women. So much of what we are able to do is after the fact, after the diagnosis of breast cancer is made.

In my daily work, I have met so many women like me. We have a common bond, and I share my story with them. It is good to know that you can have breast cancer and still have a job that you love, watch your children grow up, look forward to your grandchildren. But my heart is filled with sorrow for the loss of so many of these women, including my mother. She will never see her beloved granddaughter get married or see her first great-granchild. My dearest friend in the world, since we were 14 years old, is now fighting the good fight with her breast cancer. I never thought she wouldn't be in my life.

The medical community, today, has many resources for breast cancer patients. We have more options, more choices, now. We can have a voice in our treatment options for each patient is an individual and each diagnosis, treatment, and prognosis is different. There are tests available today that can tell us which patient will benefit from further treatment and which don't need it. This is a great step forward, but we want to know what we can do to prevent this disease from happening in the firt place. Is it only an accident of birth. The fact that we all live here might predispose us to breast cancer? Who knows the answers?

In conclusion, I would like to see more research into environmental causes for not only breast cancer, but of all the other types of cancers that are on the rise today.

Mr. WAXMAN. Ms. Johnson.

STATEMENT OF GABRIELLE C. JOHNSON

Ms. JOHNSON. Thank you, Congressman Brown and members of the panel. My name is Gabrielle Johnson and I reside in Chardon, Ohio. I am a registered nurse, a certified oncology nurse and currently coordinator of the Ambulatory Oncology and Ambulatory Surgery Units at Geauga Hospital, also in Chardon. I have worked in Geauga's chemotherapy clinic since its inception in 1980. In these past 14 years, I have seen some change, but more alarming, I have seen increasing numbers of women between the ages of 35 and 55 diagnosed with malignant breast disease. While there have been changes in treatment, many women are not well informed of their options. Women need both the information and the facts to make sound choices.

In addition to my nursing profession, I am also a wife, a mother and a breast cancer survivor. My cancer was diagnosed 16 years ago, my age at the time was 40. I am luckier than most. I am alive today, but I still live with fear. Because of my profession, I am constantly reminded that breast cancer is a systemic disease. In other words, while the breast is the body part specifically affected, breast cancer is considered to be a disease of the whole body. I must remain cognizant to the fact that my cancer could easily recur. Many patients are not aware of this nature of breast cancer and may be lulled into a sense of security as the 5 and 10 year milestones are passed.

Like many women, I found my lump myself, and within 2 weeks I had a biopsy followed by surgery. Within 4 months a lump appeared in my remaining breast and even though the biopsy revealed a benign condition that time, a simple mastectomy was advised. I knew that reconstruction surgery would be psychologically important to me, and the following year, I had the simple mastectomy followed by bilateral reconstruction. Many problems occurred with the reconstruction and I spent much of the next 2 years in and out of doctors' offices. Still, I would like to emphasize that I am luckier than many. I did not need radiation or chemotherapy and my cancer has not recurred.

My initial medical follow-up was very rigorous. I had nuclear scans and x rays at a frequency that now makes me want to shudder. I wonder what this accumulation of radiation has done or can do to my body. The pathos here is not that I was misguided, because I was not. My experience was accepted medical practice 16 years ago. It is important to remember that it is extremely difficult to question medical recommendations when your life could be endangered. These feelings are shared by thousands of women across the country, and they are also shared by Kathy and Judy and Laura who are breast cancer patients in our clinic. These women are young women. Their ages at diagnosis were 37, 44 and 50.

The oncology clinic at our small hospital has grown from 5 or 6 patients to more than 65. Breast cancer has always accounted for the highest number of patients we treat. Figures from the years 1990 to this far in 1994 indicate that an average of 37 percent of our patients are breast cancer patients. This statistic has remained constant in these past 14 years.

Kathy was a young woman of 37. She ignored her very obvious disease because she was afraid; she was afraid of surgery and she was afraid of the treatment. She also had serious insurance issues that were concerns. She subsequently required bilateral breast surgery and several courses of both chemotherapy and radiation. A bone marrow transplant was also done, but her disease had been widespread at the time of her diagnosis. We have treated Kathy in our clinic for 3 years now, but her disease is progressing. Pain has become a daily companion. Kathy is paying a very high price for her fear.

Judy sought treatment quickly. She, like I, had bilateral surgery with reconstruction. For her, chemotherapy treatment was necessary and she successfully completed her treatment in spite of severe side effects and the insult of baldness. Judy has been healthy for 3 years, but had experiences with reconstruction similar to mine. She has endured countless replacements and repositioning. She would like to put this all behind her, but cannot yet do so.

Laura was age 50 at the time of her diagnosis. She was luckily diagnosed during a routine operation. Laura came from a family with a strong malignant tendency. Both of her parents had died of cancer, a younger brother has been diagnosed with lymphoma. A previous mammogram had revealed a suspicious area 2 years before, but annual mammograms had not yet been recommended to her.

I wish all these stories had happy endings, but they do not. We all want cancer cured, but the progress is much too slow. The unfortunate truth is that there has been some progress since my diagnosis 16 years ago, but not enough. The surgical choices have changed and new chemotherapy regimes and radiation treatments offer hope to many. I am grateful that I am alive, but I want more, not only for myself but for all women living with this disease, and I speak for the Kathys and Judys and Lauras everywhere. We do not like living with the facts, it feels much too much like a time bomb. We are young women, we are wives, we are mothers. Survival rates are better, but they are still not good enough.

I feel we need to try harder to diagnose, treat and cure this cancer. The statistics tell us we are failing. We need to question where. Why is this Ohio area ranked ninth in the mortality of breast cancer?

We not only need to find out why us, but because of the major impact this has on a community, we need to increase emphasis on prevention through public screenings and awareness education, beginning ideally at a junior high level.

We also need more effective procedures for early detection. This could be achieved through affordable diagnostic testing and more readily available diagnostic systems.

And we need more affordable treatment choices. A major research effort is needed to develop more effective methods of treatment, at a cost that is not prohibitive.

Prevention, early detection and new and affordable treatments are not new ideas. They are the basis of most medicine, but we need to double our efforts here. Ohio's women want a solution. We do not want to continue to die before our time.

Congressman Brown, members of the panel, thank you for holding this hearing and thank you for struggling with this vital issue.

Mr. WAXMAN. Thank you for your excellent statement.

[The prepared statement of Ms. Johnson follows:]

TESTIMONY OF
GABRIELLE C. JOHNSON, R.N., O.C.N.

Thank you Congressman Brown, and members of the panel. My name is Gabrielle Johnson, and I reside in Chardon, Ohio. I am a Registered Nurse, a Certified Oncology Nurse, and currently the coordinator of the Ambulatory Oncology and Ambulatory Surgery Units at Geauga Hospital in Chardon. I have worked in Geauga's chemotherapy clinic since its inception in 1980. In these past 14 years I have seen some change, but more alarming, I have seen increasing numbers of women diagnosed with malignant breast disease, many between the ages of thirty-five and fifty. While there have been changes in treatment, most women seem poorly informed of their options. Women faced with these critical decisions deserve to have both the information and the facts to make sound choices.

In addition to my nursing profession, I am also a wife, mother and breast cancer survivor. My cancer was diagnosed sixteen years ago, my age at the time was forty. I am luckier than most: I am alive today, but still live with fear. Because of my profession, I am constantly reminded that breast cancer is a systemic disease. In other words, while the breast is the body part specifically affected, breast cancer is considered to be a disease of the whole body. I have been fortunate to pass the "golden" 5-year mark, and even the 10-year mark, but does my mind rest any easier? Not really. Some days I like to settle into a comfortable sense of security, but most days I remain cognizant of the fact that my cancer could easily recur. Many are not aware of this nature of breast cancer and most are lulled into a sense of security as the five and ten year milestones are passed.

Like many women, I found the lump myself, within two weeks I had a biopsy followed by a modified radical mastectomy. My only option was this surgery or doing nothing. Ignoring my diagnosis was not a choice I could accept. My surgeon was from a conservative school and though I knew that reconstructive surgery would be psychologically important to me this choice was not encouraged. It was reluctantly accepted. I waited for one year following the mastectomy on medical advice. Sooner than that, a lump appeared in my remaining breast, and even though the biopsy revealed a benign condition a simple mastectomy was advised. Fear motivated me to comply and the next year, I had a mastectomy followed by bilateral reconstruction. Problems occurred with the reconstruction and I spend much of the next two years in and out of doctor's offices. Still, I'd like to emphasize that I am luckier than many. I did not need radiation or chemotherapy and my cancer has not recurred.

My initial medical follow-up was rigorous. I had nuclear scans and x-rays of every major organ system, at a frequency that now makes me shudder. When I questioned this practice, the response was that the real danger was in not having the examination. Again, I was too frightened to question this logic. I am aware that there is truth in this concept, but now wonder what this accumulation of radiation has done to my body. The pathos here is not that I was misguided, because I wasn't. My experience was what was accepted practice 16 years ago. It is extremely difficult to question medical recommendation when your life could be endangered. These feelings are not mine alone, they are shared by thousands of women across the country and they are also shared by Laura and Judy and Kathy who are also breast cancer patients.

The hospital I practice in is a small community hospital. Our Oncology Clinic has grown from five or six patients to more than sixty-five. Since its beginning, breast cancer has always accounted for the highest number of patients we treat. Approximately forty percent of our patients are breast cancer patients and these statistics show no signs of improving. My personal observation is that breast cancer seems to be striking at a younger age. We see more and more patients between the ages of 35 and 50. The women I mentioned are young women whose ages at diagnosis were 37, 44 and 50.

Kathy a young woman of 37, ignored her obvious disease because she was afraid of surgery and treatment. Insurance issues were also a concern. For her, it was easier to deny her disease. Reality was just too frightening. She subsequently had bilateral breast surgery and serveral courses of both chemotherapy and radiation, but her disease was already widespread at the time of diagnosis. She required more radical treatment and underwent a bone marrow transplant. She has been a chemotherapy patient in our clinic for five years now, but her disease is progressing and pain is a daily companion. Kathy is paying a high price for her fear.

Judy, a patient in her forties, comes from a medical background and sought treatment quickly. She, like I, had bilateral surgery with reconstruction. For her, chemotherapy treatment was necessary and she successfully completed her treatment despite severe side effects and the insult of baldness. It was a difficult struggle. Judy had been healthy for three years but her experience with reconstruction was similar to mine. She has coped with infections and failed prosthesis, and has endured countless replacements and repositioning. She would like to put this all behind her but cannot yet do so.

Laura was age fifty at the time of her diagnosis. She was luckily diagnosed during a routine operation. When a malignancy was found subsequent screening were done and a mammogram revealed a suspicious lesion in one breast. It too proved to be malignant and surgery was again called for. Laura came from a family with a strong malignant tendency; both of her parents died of cancer. A previous mammogram had revealed a suspicious area two years before, but annual mammograms had not yet been recommended.

I wish these stories had happy endings, but they don't. I wish the medical profession could say, "Yes, it's a bad disease, but we can cure it." We all want cancer cured, but the progress is much too slow. The unfortunate truth is that there has been some progress since my diagnosis sixteen years ago, but not enough. The surgical choices have changed. Disfiguring surgery is not always necessary and preventative secondary mastectomy is recommended less. Lumpectomy can now be a safe choice and radiation and streamlined chemotherapy regimens are more common. New drugs offer hope to some women and hormone manipulation can help many. But for those of us diagnosed many years ago, it came too late. I'm still alive and I'm deeply grateful, but I want more. Not only for myself, but for all women living with this disease. I speak for the Kathys, Judys and Lauras everywhere. I don't like living with these facts, it feels too much like a time bomb. We are young women busy with our lives. We are wives and mothers and we don't want our lives prematurely snuffed out. Survival rates are better, but still not good enough.

Certainly, there is something we can actively do to fight this fatal disease. Answers must be available, if we only tried harder to diagnose, treat and cure this cancer. The statistics tell us we are failing, we need to question where.

Why is th Ohio region ranked ninth in mortality of breast cancer? We not only need to find out "Why us?" but because of the major impact this has on our community we need:

1. Increased emphasis on prevention through public screening and awareness education, beginning in the junior high level.

2. More effective procedures for early detection. This could be achieved through affordable diagnostic testing, and more readily available diagnostic systems.

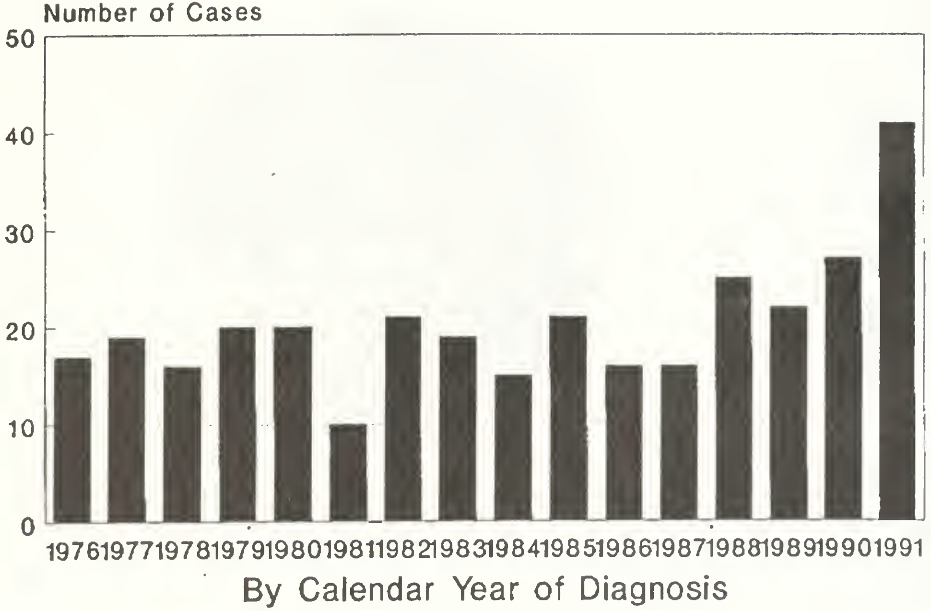
3. More affordable treatment choices. A major, research effort is needed to develop more effective methods of treatment, at a cost that is not prohibitive.

Prevention, early detection, and new and affordable treatments are not new ideas, they are the basis of most medicine, but we need to double our efforts to detect and treat this killer. The threat it poses is too great. Ohio's women want a solution and we demand that the government help us eliminate this disease. Ohio's women do not want to continue to die before their time.

Congressman Brown, distinguished members of the panel, thank you for holding this hearing and thank you for struggling with this vital issue.

Geauga Hospital Tumor Registry

Breast Cancer in Women



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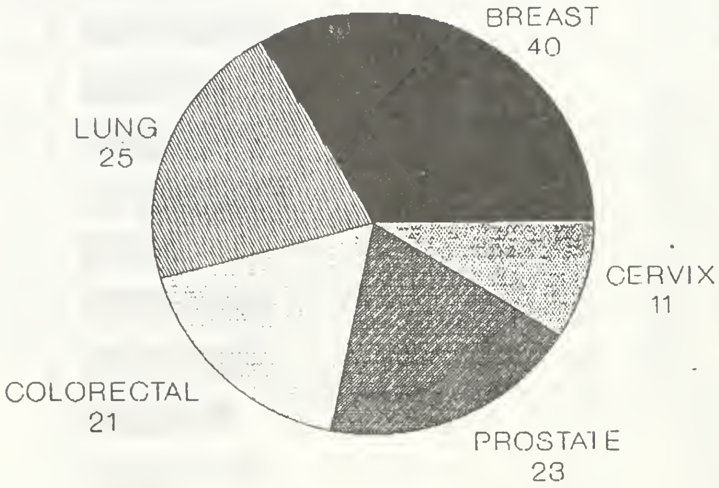
1993 CANCER CASES

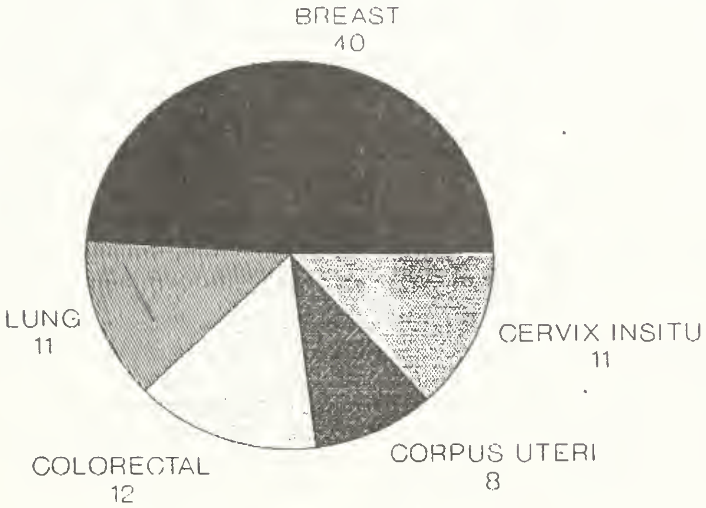
TOP 5 SITES



GEAUGA HOSPITAL

1993 FEMALE CASES

TOP 5 SITES



GEAUGA HOSPITAL

Ms. Piccioni.

STATEMENT OF RONNA PICCIONI

Ms. PICCIONI. Thank you, Mr. Chairman and members of the subcommittee. My name is Ronna Piccioni. I have been a registered nurse for 17 years and a certified oncology nurse since 1987. I am the cancer education coordinator of the Oncology Department of Geauga Hospital in Chardon, Ohio.

The area that I would like to address today are the issues pertaining to the follow-up standardization of breast cancer screenings nationally. Over the years, the response to our breast cancer screening has grown enormously. This suggests to us that the female community is indeed very interested in the subject matter and in attending this type of an event. Women who attend a screening have ample opportunity to obtain information and to have questions answered and concerns addressed.

The exams themselves are conducted by surgeons on staff at the hospital. Once the exam has been performed, a clinical diagnosis is then determined by the surgeon. A negative finding would elicit a recommendation for the woman to continue with her routine breast care consisting of mammography, a clinical breast exam and the performance of BSE or breast self-exam. A positive finding would elicit a recommendation for the woman to return as soon as possible to her primary physician for further follow-up, which may include a stat mammogram, a scheduled biopsy or even surgical intervention as deemed necessary.

We provide each woman with a copy of the clinical findings and the suggestions regarding the importance of follow-up with their own physician. Our screening programs encourage women to educate themselves and to take responsibility for their own medical care and necessary follow-up.

It has always been a much easier task to observe the individuals' follow-up when they remain within the boundaries of Geauga County. However, any kind of follow-up becomes much more difficult when the patient chooses a physician and a hospital out of the area.

I have some concerns about where the responsibilities of the screenings begin and where do they end. How can we really be sure as health care professionals and educators that the recommended follow-up is actually being done? Are the overall statistics being looked at accurately, and by whom? Should the information and data be collected and shared in order to provide a total picture as to how effective the screenings truly are on a national basis?

In looking back over 3 consecutive years of screenings at Geauga, from 1991 to 1993, it was noted that there really have been no specific diagnoses of breast cancer ever made, to our knowledge, not even after mammography and excisional biopsy for follow-up were performed on the women who did return to Geauga Hospital for a confirmed diagnosis. Since we are not seeing any positive findings through our screenings, our results are obviously not correlating with the stats that are being released by the Bureau of Chronic Diseases, by the Ohio Division of the American Cancer Society or with our own Tumor Registry at our hospital. It was also observed that the median age of these women was 53.

Since we have not had a positive case documented, this also raises a question as to whether or not we are focusing our attention on the correct target audience, or if we need to adjust that focus. One thing we do know is that regardless of age, how very important it is to educate and to reach every woman in every age category and perhaps to look more closely at our younger female population in their late 20's and early 30's and at our senior citizens in their 60's and 70's. Breast cancer findings may prove to be more significant within those age categories where the incident rates seem to be currently at their highest.

Today, there are many recommendations and guidelines available to help educators like myself, through various organizations on how to plan a screening program. However, each one is designed in its own unique style with different formats, diversified goals and objectives and a variety of methods undertaken regarding the follow-up process itself. Currently there are no two screening programs that are exactly alike across this Nation. If a woman expects a certain amount of quality regarding other services revolving around breast health and breast care, why should she not be able to expect the same high standards from a breast cancer screening? From California to Maine, a woman should be able to participate in a health screening of this type knowing that all screenings are based upon the same level of quality from coast-to-coast.

I would like to take this opportunity, Mr. Chairman, to submit my recommendations to this committee that national standards, and not just guidelines, be instituted for all breast cancer screening programs, to be practiced and followed by the screening coordinators accordingly. Screenings involving education and examinations are not just a nice thing to do. Screenings are a necessary thing to do. A well-developed screening could be one of the most important avenues we have available to us in regard to the prevention and to the early detection of breast cancer in women.

Thank you, Mr. Chairman, and members of the subcommittee, for allowing me to share my professional as well as my personal thoughts and concerns with you on this important issue that American women are facing today.

[Testimony resumes on p. 42.]

[The prepared statement of Ms. Piccioni follows:]

STATEMENT OF RONNA PICCIONI

INSTITUTING NATIONAL STANDARDS AND ACCOUNTABILITY FOR HEALTH CARE EDUCATORS AND SCREENING COORDINATORS OF BREAST CANCER SCREENING PROGRAMS IN THE UNITED STATES

Thank you, Mr. Chairman, and members of the Subcommittee on Health and the Environment for this opportunity today. My name is Ronna Piccioni. I have been a Registered Nurse for 17 years and a Certified Oncology Nurse since 1987. I have been with Geauga Hospital since college graduation and I am presently in the position of Cancer Education Coordinator of the Oncology Department. Geauga Hospital is located in Geauga County of Chardon, Ohio and is a 169 bed facility. The hospital's main focus is in Orthopedics, Sports Medicine, Obstetrics and in Oncology Care.

My nursing background includes previous experience in chemotherapy administration, providing bedside care to oncology patients, including Hospice cases; providing Enterostomal therapy services and developing and implementing community health and educational programs on various levels.

The area that I would like to address today, are the issues pertaining to the implementation, the outcome potential and the standardization of a formalized Breast Cancer Screening Program on a national level for Health Educators and Screening Coordinators.

Allow me now, to take you through the developmental stages of our screening program and to highlight for you, not only the advantages but also the disadvantages we have incurred in our attempt to provide the very best screening service to our female community.

Our present means of advertising the screening event consists of local newspaper advertising, as well as, publishing informational articles. These are also published in Cleveland Magazine and the

Cleveland Plain Dealer. The ads are also placed on local cable stations throughout Geauga and surrounding counties for increased visibility. In the past, we have been featured on local radio stations as well. But our largest volume of publicity is derived from our direct mailings to Geauga County households and posting fliers throughout the county in drugstores, local shopping areas, county-wide libraries, churches, school systems and at the local Senior Center.

For the process of program registration, we utilize three modalities that the community can access (keeping in mind the importance of accommodating our Amish and our elderly community). Individuals can register by telephone, by mail or they can register in person, directly with the Oncology Department.

Over the years, the response to the Breast Cancer Screening has grown enormously and we are usually booked at least two weeks in advance. This suggests to us that the female community is indeed, very interested in the subject matter and in attending this type of an event. Our crowd capacity for the event is limited to only 80-100 people, due to room size and availability on the hospital grounds.

Since we usually have a substantial waiting list of women who would like to be kept in mind if someone cancels or does not show, we do make reminder calls to all ladies booked for a clinical exam. The reminder call thus allows us to add or delete, as necessary, and to remind ladies about the importance of keeping their appointment and bringing their most recent mammography films with them.

The difficulties regarding transportation to the screening site have always been a concern for us. Those who do not own a vehicle or have access to using the local transit system, are usually not able to attend. Many of our elderly complain of visual or physical handicaps, night blindness or even a fear of driving after dark. Even though the screenings in the past have been free, many elderly still cannot pay the extra monies required to cover transportation costs.

Rescheduling the program and the examinations to the day-time hours would still not solve this problem for us. Since the surgeons provide the Clinical Breast Exams (C.B.E.'s), the screenings have been scheduled at a time of the day that would not interrupt with the surgery schedule in the operating room, as well as with their own private practice and office hours.

The Amish community, still dependent upon a horse and buggy as their main source of transport, do call upon local cab companies as needed but there is still a considerable expense for the service. Since we usually see very few, if any, Amish attend any kind of an educational program at the hospital, we do make an effort to go to them several times throughout the year---taking part in Health Fairs co-sponsored by The Department on Aging or by the Amish community itself. This has not given us the opportunity to perform Clinical Breast Exams (C.B.E.'s) to date, but it has provided us with an avenue to get general information to them on prevention and early detection of breast cancer.

When the individual arrives at the screening program, they will have ample opportunity to obtain information and to have their questions answered and their concerns addressed. We mix education with fun, which always makes the learning process a more pleasurable and memorable one.

Following the educational portion of the program and while waiting for their screening examination, the educational process continues with the availability of informational display tables and videos that they can view on the subject matter of B.S.E. and early detection and intervention.

The examination itself is conducted by a surgeon on staff with the hospital and is assisted by an R.N. Once the exam has been performed, a clinical diagnosis is then determined by the surgeon.

*A negative finding would elicit a recommendation for the woman to continue with her routine breast care, consisting of: mammography, a Clinical Breast Exam (C.B.E.), by her Primary Care Physician on an annual basis and to perform Breast Self-Exam (B.S.E.) on a monthly basis.

*A positive finding would elicit a recommendation for the woman to return, as soon as possible, to her immediate Primary Care Physician for further follow-up. This follow-up may include: a stat mammogram, a scheduled biopsy or even surgical intervention, as deemed necessary.

We provide each woman with a copy of a form entitled, "Record of Visitation" and on this form are included all of the clinical findings that were made and the suggestions regarding the importance of follow-up with their own Primary Physician. If a woman does not have a Primary Physician and is interested in seeking one, we encourage her to contact our Medical Staff Secretary at the hospital and a listing of the Medical Staff could be mailed to her directly. The screening program encourages women to educate themselves and to take responsibility for their own medical care and necessary follow-up.

It has always been a much easier task to observe the individual's follow-up when they remain within the boundaries of Geauga county. However, any kind of follow-up becomes much more difficult when the patient chooses a physician and a hospital out of the county area. I have some concerns about where the responsibilities of the screenings begin and where do they end. How can we really be sure, as Health Care Professionals and Educators, that our recommended follow-up is actually being done. Are all the proper connections being made and are the overall statistics being looked at accurately and by whom. I believe you will see, more clearly, my concern for those women we lose contact with regarding follow-up, as I present to you Geauga Hospital's screening results from 1991 to 1993.

In 1991, approximately 70 people attended the program and 27 examinations were performed. Four (4) women were referred for follow-up. Three (3) were found to be benign and one (1) was referred to her Primary Care Physician who was located outside of Geauga County.

In 1992, over 90 people attended the program and 51 exams were completed. Four (4) women were referred for necessary follow-up. Three (3) of these cases were referred back to Primary Physicians, all with practices outside of Geauga County and the fourth case was seen at Geauga Hospital---biopsy was performed and the results were negative.

In 1993, approximately 80 people registered and 59 exams were done. Two (2) women were found to have significant findings. One (1) case was biopsied at Geauga Hospital and found to be negative and the other case was referred back to the Primary Care Physician, who was once again, out of the county boundaries.

In looking back over these three screening events, there really have been no specific diagnoses of breast cancer ever made to our knowledge, not even after mammography and excisional biopsy for follow-up were performed on the women who did return to Geauga Hospital for a confirmed diagnosis.

It remains unknown as to how the women did who chose a physician and a hospital outside of the Geauga County area. Since we are not seeing any positive findings through our screenings, our results are obviously not correlating with the statistics that are being released by the Bureau of Chronic Diseases or by The Ohio Division of the American Cancer Society.

It was also noted that the average age of these women who attended the screenings was 53. Since we have not had a positive case documented, this also raises the question as to whether or not we are focusing our attention on the correct target audience or if we need to adjust that focus.

We know that regardless of age, how very important it is to educate and to reach EVERY WOMAN in EVERY AGE category; however, perhaps we need to look more closely at the younger female population (in their late 20's and early 30's) and the senior citizen in her 60's and 70's. Breast cancer findings may prove to be more significant within those age categories where the incident rates seem to be currently at their highest.

Geauga Hospital participates, annually, in a Skin Cancer Screening Program coordinated by The American Dermatological Society. It is an event that is correlated with a local T.V. station and our local Cleveland Dermatological Society. A specific time of the year is selected---a phone bank is available on a particular day to assist with registration---and there are specific instructions and standardized forms which were designed for this particular screening event. It is a powerful and a highly successful screening for us and one that we have always enjoyed participating in. Conducting breast cancer screenings along these same lines would hopefully provide us with the ability to compile statistics and to compare with one another, giving us the overall picture of how effective the screenings truly are.

In my closing statement, Mr. Chairman, my attempt today is to present to you and to this committee, my concern for how breast cancer screenings are being conducted across this nation. Screenings are being conducted without specific standards.

Currently, there are many recommendations and suggestions available to Health Educators, like myself, through various organizations, ie: The American Cancer Society and the National Cancer Institute on how to plan a screening program; however, each one is designed in its own unique style with different formats, diversified goals and objectives and various methods undertaken regarding the follow-up process itself. There are really no two screening programs that are exactly alike across this nation.

If a woman expects a certain amount of quality regarding other services revolving around breast health and breast care, why shouldn't she be able to expect the same high standards from a breast cancer screening. From California to Maine, a woman should be able to participate in a health screening, of this type, knowing that all available screenings are on the same level of quality from the program format to the policies and procedures---especially protocals regarding follow-up care.

I would like to take this opportunity, Mr. Chairman, to submit my recommendation to this committee that NATIONAL STANDARDS and not just guidelines, be instituted for all breast cancer screening sites to be practiced and followed, by the Screening Coordinator, accordingly.

Screenings, involving education and examinations, are not just a nice thing to do. Screenings are a necessary thing to do. A well-developed screening could be one of the most important avenues we have available to us in regard to the prevention and to the early detection of breast cancer in women.

Thank you, Mr. Chairman, and members of this Subcommittee for allowing me to share my professional, as well as, my personal thoughts and concerns with you on this important issue that American women are facing today.

THIRD ANNUAL BREAST CANCER EDUCATIONAL & SCREENING PROGRAM

THE ONCOLOGY DEPARTMENT
OF
GEAUGA HOSPITAL
&
THE AMERICAN CANCER
SOCIETY--GEAUGA UNIT

PRESENTS

THE THIRD ANNUAL BREAST CANCER EDUCATIONAL & SCREENING PROGRAM

WHEN:	Tuesday, October 26, 1993
WHERE:	Geauga Hospital, Third Floor Conference Room
TIME:	5:30-6 p.m.: Registration; Appetizers; & Welcome 6:00-6:45 p.m.: Educational Program-"Early Detection of Breast Cancer in Women" Presented by Susan Schommer,M.D. 7:00-9 p.m.: Professional exams performed in private, by physicians of Geauga Hospital

****

To register for the conference and to schedule yourself for a FREE PROFESSIONAL BREAST EXAMINATION, please call:
The Oncology Department of Geauga Hospital at 285-6125, 834-6125, 269-6125, 1-800-548-9738 ext. #6125, weekdays 8:00 a.m. to 4:00 p.m.

Advance Registration for the conference and for the FREE EXAM is a MUST. Registration will be limited.

October is National Breast Cancer Awareness Month--Call us TODAY for your reservation---Because "YOUR HEALTH IS IMPORTANT TO US

geauga hospital

Education Department

ESTIMATING YOUR PERSONAL CHANCES OF DEVELOPING BREAST CANCER

Every woman is at risk of breast cancer simply because she is a woman! (In fact, 99 out of 100 breast cancers appear in women). The SELF-QUIZ below lists the risk factors of developing breast cancer. It will only take about a minute of your time to pinpoint your personal chances of developing breast cancer.

RISK FACTOR	CATEGORY	POINTS	SCORE
YOUR AGE	UNDER 30	10	
	30-40	30	
	41-50	75	
	51-60	100	
	OVER 60	125	
YOUR FAMILY HISTORY	NO BREAST CANCER	0	
	1 AUNT OR 1 GRANDMOTHER	50	
	MOTHER OR SISTER	100	
	MOTHER AND SISTER	150	
	MOTHER AND 2 SISTERS	200	
YOUR HISTORY	NO BREAST CANCER	0	
	PREVIOUS BREAST CANCER	300	
CHILDBEARING	FIRST BABY BEFORE AGE 30	0	
	FIRST BABY AFTER AGE 30	25	
	NO CHILDREN	50	
MENSTRUAL HISTORY	BEGAN MENSTRUATING AGE 15 OR OVER	15	
	BEGAN MENSTRUATING AGE 12-14	25	
	BEGAN MENSTRUATING AGE 11 OR UNDER	50	
BODY TYPE	SLENDER	15	
	AVERAGE	25	
	OVERWEIGHT	50	
		TOTAL SCORE	

Your total score gives only a general indication of your present risk category. If you develop ANY *symptoms, see your doctor at once.*

IF YOUR SCORE IS . . .	YOUR CATEGORY IS . . .
UNDER 200	LOWEST RISK
201 - 300	MEDIUM RISK
301 - 400	HIGH RISK
OVER 400	HIGHEST RISK

Provided by: "The Good News About Breast Cancer"; Health Edco, Inc.,
by W. R. Spence, M.D.

Rev: 6/89 6/90

CANCER SCREENING PROGRAM
HISTORY FORM

IENT INFORMATION:

Previous hospital visit? ( ) yes ( ) no Phone____________________

Client Name:____

Address:____

GUIDELINES: *(Mark Yes, No, N/A)*

a.) What is your age...______________
b.) Are you pregnant at this time?......................................( )yes ( )no ( )N/A
c.) Are you breast feeding at this time?..............................( )yes ( )no ( )N/A
d.) Approximate date of your last menstrual period...............______________
e.) Have you ever had a mammogram before?.......................( )yes ( )no
f.) Where was your mammogram done? Facility.................______________
g.) When was your last mammogram done? Approx. date....______________
h.) When was your last breast exam done by a physician?
Approx. date.....______________
i.) Name of physician, if any, to whom screening results should be sent:

____
Name

____
Address

Results sent? ( ) yes ( ) no Date:____________________

HISTORY (Info to be obtained from client by Health Care Educator)

a.) Is there any history of breast cancer in your family?............( )yes ( )no
If yes, who is it? (relationship—Mother, etc.)______________

b.) Do you have a history of breast cysts?.............................( )yes ( )no
c.) Do you feel any breast lumps?..( )yes ( )no
d.) Do you have a history of breast surgery?..........................( )yes ( )no
e.) Number of children...______________
Your age at the time of your first birth..............................______________
f.) Are you a smoker?...( )yes ( )no
If yes, number of years______________Amount per day______________

g.) What is your daily caffeine intake..................................______________
h.) What medications are you taking presently?______________

____
Birth control pills?...( )yes ( )no

10/93

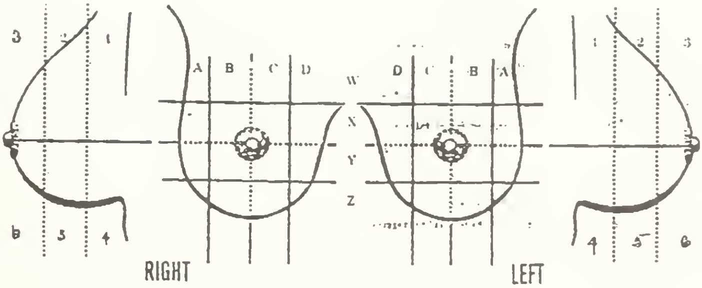
GeaugaHospital

F. PHYSICIAN'S USE ONLY

BREAST SYMPTOMS:

Scars................ ☐ Rt. ☐ Lt.
Lesions.............. ☐ Rt. ☐ Lt.
Tenderness........... ☐ Rt. ☐ Lt.
Nipples Inverted..... ☐ Rt. ☐ Lt.
Lumps................ ☐ Rt. ☐ UOQ ☐ LOQ ☐ IUQ ☐ ILQ
☐ Lt. ☐ UOQ ☐ LOQ ☐ IUQ ☐ ILQ

Moles............... ☐ Rt. ☐ Lt.
Burning............. ☐ Rt. ☐ Lt.
Nipple Discharge.... ☐ Rt. ☐ Lt.



Mr. WAXMAN. Thank you very much, Ms. Piccioni.

I want to thank each of you for your testimony. It was very poignant testimony and it is not easy, I am sure, to talk in public about something so personal as your own experiences with breast cancer. But I want to thank you for your courage and commitment and I think it is going to make a big difference in the lives of many other people, that you were willing to come and share this with us.

Ms. McGreer, you described a horrendous situation of not knowing from the early mammography tests, what was going on. Let me ask you and maybe others on the panel as well, there is so much more we want to do, but would you still recommend that women get mammographies?

Ms. MCGREER. I believe that if I had a good mammogram that was read better, that I would have known—it would have been confirmed a week later—that something was wrong. I followed up consequently at Mt. Sinai. We discussed the mammogram and they said that even their own people were uncertain, but I was told that at Mt. Sinai, they would have followed up, they would not have just sent me home saying everything was OK; there would have been additional follow-up. So even in my case, although I did not detect it until 8 months later, when it was very clear, I believe that it could have.

I spoke to the radiologist, I politely backed him into a corner and he made all these excuses about well it was not that good a mammography machine. He said if I sent a whole lot of false negatives back to the doctors, women will get upset, doctors will get upset. I said to him if this was cancer in November, this was cancer in March. When you see another one like this, think of me and do a little better.

So yes, I believe in mammograms.

Mr. WAXMAN. You have described how you have been able, all of you, to deal with the maze of health care services and support systems and resources that you found to be available and some of you are now personally involved in providing those services. What recommendations do you have for us, those of us who are working on a health care bill to try to provide services for all Americans? Or for those of us who have oversight jurisdiction over the Institute of Medicine and the National Cancer Institute. From your own experiences, what would you recommend we take back to the medical community to make the system more user-friendly and any other thoughts.

I know, Ms. Piccioni, you said you have some specific recommendations on national standards, and I appreciate that. But any other specific recommendations that any of you want to make.

Ms. DUCKWORTH. I do.

Mr. WAXMAN. Yes, Ms. Duckworth.

Ms. DUCKWORTH. I want to see much more public awareness. I do not just mean—and I have seen this happen many, many times—women will pick up a popular magazine and there will be a story, breast cancer-related story, or why did breast cancer happen to this particular person, and they panic, women panic, patients panic. We read too many mammograms are dangerous because of the radiation. We take certain medications, you know, they can cause other problems. It is a calculated risk, you have to decide what is right for you to do and I would like to see more public awareness. You read these articles in the paper and I can guarantee you that every time it happens that phone rings off the hook in the office the next morning. I am scared, I do not know whether to take—whatever it is—any more, I am not going to take it any more because it can cause this and it can cause that. Well what are you going to do—I am going to keep on taking whatever it is if that is what I feel is going to help me. But it is sensationalized so much, and we need more public awareness of, you know, what to do and how to do it.

Mr. WAXMAN. Good point. Yes, Ms. McGreer.

Ms. MCGREER. I think we have to maximize the knowledge that we already have. It was my experience to have a bad mammogram on a not very good machine and it is appalling to think that nationally it is being said that mammograms do not do much for women under 50. As I stated, everybody I knew was under 50, 2 were under 40. I had a very different exam from Dr. Levy—well all the way over to here—as opposed to my very dear OB-GYN who examined only my breast. So I think there has to be some standardization, as was suggested at the end of the table.

I am very concerned about the halt of research. And yes, there have been mistakes made, but this is our only answer and we in northeastern Ohio know all about chuckholes. Yes, there are some chuckholes here, but you do not stay home because of chuckholes. We have decisions being made about the treatment of people in the future based on the willing 2 percent of people now who will be involved in these clinical trials. We need to go forward with research. We have to investigate what needs to be investigated, but not to stop-—to go forward.

I am very concerned about health care reform. I believe that freedom of choice means better health care. And more than once in my life I have been able to freely choose a doctor from anywhere, and it has been to the betterment of my health, and so I am very concerned about any restrictions that may be forthcoming in health care reform plans.

I do not know what the government can do to help women be strong and brave. I think we have to get together with each other, share our stories and learn to listen to our emotions but also listen to our intellects and make good medical decisions.

Mr. WAXMAN. Thank you.

The government can do a lot, but far more important I think, in terms of communications, is hearing from you, those of you who have gone through this experience and worked first-hand with breast cancer, to talk to other women and to give them some sense of encouragement and some sense of what it is to go through the experiences that you have had.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Ms. McGreer, you were 46 at the time of your diagnosis; Ms. Duckworth, I believe you said you were 40; Ms. Johnson, you said you were 39.

Ms. JOHNSON. I was 40.

Mr. BROWN. I am sorry, you were 40 and you were 39. And you mentioned, Ms. Johnson, Kathy and Judy, both of whom were under 40, and I believe you, Ms. Duckworth, mentioned—or Ms. McGreer, you mentioned the people in your neighborhood that were all young. In light of the Department of Health saying 51 percent of women over 40 said they did not receive a mammogram because their physician did not recommend it and about a third of women say they did not know it was necessary. Partly following up with Chairman Waxman's question, what do we on this panel do about that and what do you say to those doctors and what do you say to your daughters and your sisters, and what do we say to our wives and our mothers about all of that, to make sure that early detection is more the order of the day?

Ms. JOHNSON. I think if we educate people to not be afraid to realize if they find a lump, to seek treatment early on, you stand a better chance of catching the disease in the earlier stages. So they have to be not afraid.

Our community is rural; we have a high Amish population. They are very reluctant to examine their bodies. I feel like it needs to be taught early on that this is an important thing to do.

Mr. BROWN. Ms. McGreer, particularly what do we do about doctors that are saying—that survey was actually of women over—they asked doctors—women over 40 what their physicians were saying to them, and let alone to women under 30. What do we need to do with the medical community to make them see and understand and encourage them to talk to their female patients more about this?

Ms. MCGREER. Well I can imagine that doctors do not like a lot of regulation. A lot of doctors feel very much they are an entity unto themselves. But perhaps there should be some guidelines—if you are going to be in the field of caring for women, then perhaps you should attend conferences to update yourself. I was very surprised to find that the breast specialist treated me in a different way from the doctors that I knew and trusted, with a different exam, a different needle biopsy, a better mammogram. Perhaps they should be required to have additional education, a certificate of some type showing that they have fulfilled all the requirements so that they are really most capable of diagnosing and treating.

Mr. BROWN. Ms. Piccioni, you mentioned the screening program in Geauga County, in Geauga Hospital, and you talked—I appreciate your input on the recommendations to do better standardizing of screening nationally. Do you have experience in being able to contrast what Geauga Hospital's screening program looks like compared to—contrast it with other programs in northeast Ohio? Do you have any feel or understanding of what other hospitals and providers are doing?

Ms. PICCIONI. In talking to other hospital education coordinators who are doing the screening events, I think that we fall all into the same category. I think we are all doing the same types of things. I do not know if we are seeing similar results but it is the follow-up process that really concerns me.

We educate these women, we recommend to them what is the best thing for them to do and then we let them go. And there is no follow-up thereafter unless they happen to come back to our hospital. I think if we could follow a little bit more closely or somehow be able to compile data and share stats with each other, we would be able to see where these people are going, what is happening to them, if the screens being effective. I mean why do this just to get a bunch of women together and have appetizers and talk about breast care. It has to be more than that. It has to be important, it has to be significant because it is serious, this is serious business.

And I would just like to make a comment about the physician involvement. When we request a surgeon to participate in our breast cancer screenings, that is an opportune time for us to educate them. So if they have questions about current treatments or standardizations or education, that is when we load them up with information from the National Cancer Institute or the American Cancer Society or things that they are not familiar with on a daily basis. So we all educate each other. I think that is an opportune time. And they get motivated and we get motivated and we all get excited and we do what we think is a fantastic job in our screenings, but still there is something lacking and that is what I would like to see improved.

Mr. BROWN. Do you think that is the case for most hospitals in northeast Ohio, the screening tends to be pretty standardized and tends to be accurate and effective, the follow-up is less than desirable sometimes?

Ms. PICCIONI. Basically everybody has their own forms, their own histories, their own questions. There is nothing standardized across the board. There is a lot of suggestions and they are good. I mean I have a wonderful resource booklet that we can go to and look up and whatever, but nothing is the same and I think that we falter there. I think that we could do better there. I think we would get clearer answers and perhaps earlier detection—I really believe that.

Mr. BROWN. Ms. Johnson, as a nurse oncologist and as a breast cancer survivor, you pointed out the increased incidence in breast cancer in Geauga Hospital, cases in Geauga Hospital. What do you attribute that large increase to? Give us some thoughts and maybe the three of you, if you want to pursue that, but particularly in Geauga County, the two of you, if you have some thoughts on why the incidence has increased so dramatically.

Ms. JOHNSON. I really do not know. It could be so many different things, and it could be purely population growth. I just know we are seeing more and more; we are treating many more. I do not know if women are more aware and so they are seeking treatment maybe earlier, but not early enough. As far as why the incidence is rising, I do not know and I think that is why we are here today.

Mr. BROWN. Ms. McGreer.

Ms. MCGREER. As I sat waiting for my pre-op tests, I read an article in a woman's magazine that analyzed a person's risks of breast cancer. If I had moved back prior to having any problems at all, I would have had a 2 percent risk. There was no history in the family of breast cancer. I had six children. I had them early, I nursed them—you know, I did many of the things that seem to lead away from breast cancer, and yet there I was in that 2 percent.

I am not a scientist. I can only sort of guess or feel that somehow it is an accumulation of factors that eventually comes around to get some of us. My young neighbor, Ben, who died was a UPS driver and when they looked at all his blood work, they said what on earth have you been exposed to. You know, the neighborhood thought, "Are we sitting on a time bomb?" or what, you know, he was a UPS driver, perhaps there was something there. But I feel that it is probably some total accumulation of exposure to things that may increase the estrogen level. And yet who wants women with no estrogen—that is not much fun either.

Mr. BROWN. The three of you that work directly with cancer patients, let me direct my last question to the three of you. Do you have any evidence of any sort of geographic or any other way of determining where more cancer patients, more breast cancer patients may be coming to you? In Geauga County, is it centered around any particular community, and in your work in Lorain County, Ms. Duckworth, are you seeing it around any plant or around—are you seeing a lot in farm areas or around a certain water source? Anything like that you can give to this subcommittee, or if you cannot today, think about and perhaps give to us at a later time. Any comments from the three of you on any of that?

Ms. JOHNSON. Specifically, I do not. They are located pretty much randomly across the county and not all congregated in one specific area. I think we have seen a county map with instances, but like I say, they are pretty well distributed evenly.

Mr. BROWN. And Geauga is a pretty mobile county, people—there are a lot of new people that have moved in, more so than Lorain.

Ms. JOHNSON. That is right.

Mr. BROWN. Ms. Piccioni, do you have any thoughts about that?

Ms. PICCIONI. My comment would be the same as Gay's; we see it scattered as far as incidence goes.

There was a study that was done by a doctor from the hospital, who is also on staff at Case-Western Reserve University in Cleveland. And perhaps we could introduce that as information. It was a 1991 study and it pretty much showed the incidence of breast cancer in specific areas.

Mr. BROWN. That would be helpful.

Ms. Duckworth, any thoughts?

Ms. DUCKWORTH. Our patient population is Lorain, city of Lorain, Elyria, Amherst, Vermillion, some of the small little towns. We have a lot of patients coming from Cuyahoga County. We have patients that come in from overseas. So it is hard to say, I cannot say a specific pocket. I think that would be something to look into though.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Brown. Thank you very much for your testimony; we very much appreciate it.

Our next panel of witnesses will discuss the impact of breast cancer in Ohio, particularly the northeast part of the State. Dr. Peter Somani is the director of the Ohio Department of Public Health. Representing the National Breast Cancer Coalition is Ms. Nancy Chilcote. And Ms. Glynis Laing joins us from the hospital where we are meeting today, St. Joseph's Hospital and Health Center. Ms. Laing serves as the hospital's Program Manager for Cancer Services. We would appreciate it if you would come forward.

I would like to welcome you here today. We appreciate your being here with us. Your prepared statements will be in the record in full. We would like to ask, if you would, to limit your presentation to around 5 minutes.

Dr. Somani, why don't we start with you.

STATEMENTS OF PETER SOMANI, DIRECTOR, OHIO DEPARTMENT OF HEALTH; NANCY CHILCOTE, NATIONAL BREAST CANCER COALITION; AND GLYNIS LAING, PROGRAM MANAGER FOR CANCER SERVICES, ST. JOSEPH'S HOSPITAL AND HEALTH CENTER

Mr. SOMANI. Thank you, Mr. Chairman, Congressman Brown, Honorable Kate Walsh—I see she just left, distinguished colleagues on the panel, fellow citizens of the State of Ohio. I am Dr. Peter Somani, Director of the Ohio Department of Health. Thank you for giving me the opportunity to discuss breast cancer in northeast Ohio and to describe what the Ohio Department of Health is doing to address the problem. My testimony today will provide you with some numbers and statistics, but most importantly it will also illustrate that Ohio is in a unique position to alter the trends observed in recent years, and to address some of the concerns you have heard this morning.

I would like to address first does Ohio, especially northeast Ohio, present a unique breast cancer problem. According to the latest data obtained in 1992, Ohio's experience is much like that of the Nation as a whole. Nationwide and among women in Ohio, breast cancer is a leading cause of illness and death.

The breast is the most frequent site of cancer in Ohio's women and breast cancer is Ohio's second leading cause of cancer deaths among women, following lung cancer as the number one cause.

We will be using data obtained by the Ohio Cancer Incidence Surveillance System set up in 1992 statewide, pursuant to House Bill 213 as sponsored by Representative Kate Walsh from this area. We can further examine the problem of breast cancer by region of the State and county-by-county. This allows us the opportunity to analyze the information a lot more closely than was possible in the past.

Allow me to make a few comparisons of breast cancer incidence rates for northeast Ohio and the State as a whole and compare that to the national figures.

In 1992, 6,978 Ohio women were newly diagnosed with breast cancer. This results in an age-adjusted rate of 101.4 per 100,000 women. This rate is slightly lower than the United States rate of 108.8 per 100,000 women. These rates are adjusted for age and therefore, they are easy to compare. During 1992, there were 3,099 cases of breast cancer diagnosed among women in 22 counties that comprise northeast Ohio. This results in a rate of 104 per 100,000 women. And this chart shows that the results as a whole are comparable for northeast Ohio and Ohio as a whole and the Nation.

We know that a woman's risk of breast cancer increases with age. For example, at age 30, a woman has a risk of 1 in 2,525, but as the woman begins to age—as we heard also this morning—the risk for breast cancer continues to increase and by the time the woman reaches age 85, the risk increases to 1 in 9.

The age-specific rate for women in northeast Ohio shows the same trend. The risk for breast cancer rises with increasing age. Some of you in the back may not see this, but if you will look at the graphs for United States as a whole, Ohio in general and northeast Ohio, the graphs are almost overlapping. For example, the rate of women age 30 to 34 is 22 per 100,000 women; for the age group 80 to 84, the other end of the graph, the rate is 439 per 100,000 women. It is important to note that the age-specific rates for Ohio and northeast Ohio are comparable to the rates for the United States overall. However, for Cuyahoga County, Lorain County, Medina County, the rates for women under age 50 for 1992 figures, are higher than either of those for Ohio or for the Nation as a whole. I will be happy to talk about some of these details in questions and answers.

The second question that has been posed that I would like to address is, what do we know about preventing breast cancer.

Unfortunately, as we heard also this morning, there are no known ways to prevent breast cancer. Certain risk factors may play a role in the development of the disease, but we cannot pinpoint a direct relationship between any woman's breast cancer and a single cause.

The factors that contribute to breast cancer include increasing age, family history, having no children, delayed childbearing, early menstruation, late menopause, high fat diet, lack of exercise, tobacco smoking and excessive alcohol consumption. And as one can judge from this list, it clearly points out that we really do not know exactly what causes cancer of the breast. We also do not know the exact relationship or inter-relationship of these risk factors. It is quite obvious, as we heard this morning, that we are also dealing with some cases that cannot be explained easily by these known risk factors.

Since we cannot effectively know what are the risks, we must focus our efforts on the early detection of the disease. The survival rate is over 95 percent when breast cancer is diagnosed in early stages.

Tools for early diagnosis include breast self-exam, where a woman is trained to regularly examine her breasts for signs of cancer; clinical breast examination by a physician or other trained health care professional; and by mammography, where a woman's breasts are radiologically screened for signs of cancer. The Ohio Department of Health recommends that women in Ohio follow the American Cancer Society's breast cancer early detection guidelines and these are provided in my written testimony.

Despite these recommendations, the studies reveal that breast clinical examination and mammography are under-used, particularly in Ohio and you already heard from Congressman Brown some of the information that Ohio Department of Health has been able to gather. In Ohio, only 50 percent of women over the age of 40 are meeting the American Cancer Society's and Ohio Department of Health's mammography screening guidelines. Ohio women give many reasons why they are not getting these screening tests. And you also heard from Congressman Brown some of the reasons. And therefore we have a strong task ahead of us to provide public awareness and public education.

So what is the Ohio Department of Health doing to reduce breast cancer in Ohio?

Many important components of combating breast cancer are already in place in Ohio. The first is Ohio's statewide cancer plan, "The Ohio Cancer Plan 1992—2000", and a copy of this is being provided and is available in the back. This plan establishes reasonable cancer reduction goals for the year 2000. With respect to breast cancer, the plan concentrates on putting in place strategies for early detection, improved access to affordable mammography screening, quality assurance for mammographies and cancer surveillance to more effectively target intervention strategies. The Ohio Department of Health is moving ahead in each of these areas.

I am pleased to report that the Ohio Department of Health has received a $2.7 million grant from the Federal Centers for Disease Control in our efforts to implement these strategies. Authorized by the Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354, this project promotes educational programming for Ohio's women and their families and also includes a systematic component of professional education. The CDC funds are being used in Ohio to establish regional projects which will reimburse providers for delivery of early detection services, including paying for mammography for those who are unable to pay for such screens.

For women with abnormal screening results, case management assistance for follow-up diagnostic services and treatment will also be provided. In addition, working with the Ohio State Medical Association and American Cancer Society, Ohio Division, we are also developing professional education plans so that the health care professionals will be made aware of the details of breast cancer in women.

Under these programs, four multi-county pilot projects received funding starting in January of 1994. The remaining projects will receive funding beginning September 1 of this year. The Ohio Department of Health has requested an additional $1.8 million in Federal funding to further expand the project in its second year.

One of the regional pilot sites for this project is in northeast Ohio. The Cuyahoga County Board of Health has worked quickly and effectively to collaborate with providers and community agencies to put their project in place. These services are now beginning to be made available to eligible women throughout a five-county region which includes Lorain County.

Let me quickly review, Mr. Chairman and Congressman Brown, the Department of Health's other cancer-related activities:

1. We have the Ohio Cancer Incidence Surveillance System established in 1992. This allows us to collect information of all newly diagnosed cancer cases throughout the State of Ohio. Even if a person may live in Lorain County, but if the diagnosis is made in Cuyahoga County, for example, that person will be included in our surveillance program.

2. We have been supportive of the recently elected legislation, House Bill 142, which requires insurance companies to offer coverage for mammograms. This is one mandate that Governor Voinovich was willing to agree to and has signed the bill into law.

3. We are embarking on a program for licensure of mammographic facilities to assure quality standards.

4. We have recently created—and I believe one of the very few States that have this—Ohio has created in its statutes the Office of Women's Health Initiatives and we have the Director of that program with me this morning. She will be focusing on many of these issues, including the issue of breast cancer in women.

In addition to the Department's activities, our First Lady, Janet Voinovich, who is a long-time advocate of breast cancer awareness, has participated with the Department of Health, and with the American Cancer Society in making women aware of these breast cancer problems. She will continue to travel throughout the State of Ohio during the month of October, which is designated by Governor Voinovich as "Breast Cancer Awareness Month." One of those stops will be in Cleveland.

Finally, let me just share with you what women can do for themselves to reduce their risk of breast cancer. We already have heard this morning that it is very important for women to be aware of the risks. It does not have to do with race. Personal choices are important, particularly about smoking, eating a balanced low fat diet, exercising. Looking at all those risk factors and taking into account the recommendations that we have made about breast self-examination, awareness of the possibility of developing cancer, appropriate clinical examination and mammography.

I would like to conclude my testimony by acknowledging the tireless efforts of many other organizations and agencies throughout Ohio that have worked with us in reducing breast cancer morbidity and mortality.

I am optimistic that the Ohio Department of Health, with our many partners statewide, and with the continued support of the Federal Government, can meet our State's year 2000 breast cancer reduction goals.

Thank you very much again for allowing me to testify this morning.

Mr. WAXMAN. Thank you very much, Dr. Somani.

[Testimony resumes on p. 64.]

[The prepared statement of Dr. Somani follows:]

STATEMENT OF PETER SOMANI

BREAST CANCER IN OHIO

The Honorable Congressman Brown, Chairman Waxman, members of the Subcommittee on Health and the Environment, distinguished colleagues, and fellow citizens of the State of Ohio, I am Dr. Peter Somani, director of the Ohio Department of Health. Thank you for the opportunity to discuss breast cancer in Northeastern Ohio and to describe what the Ohio Department of Health is doing to address the problem. My testimony today will provide you with numbers and statistics, but most important, it will also illustrate that Ohio is in a unique position to alter the trends observed in recent years.

Does Ohio, especially Northeastern Ohio, present a unique breast cancer problem?

According to our latest data, Ohio's experience is much like that of the nation as a whole. Nationwide and among women in Ohio, breast cancer is a leading cause of illness and death. An analysis by the Centers for Disease Control in 1986 revealed that Ohio women have the ninth highest age-adjusted breast cancer mortality rate in the nation.[1]

The breast is the most frequent site of cancer in Ohio's women, and breast cancer is Ohio's second leading cause of cancer deaths among women, following lung cancer. Breast cancer represents about 32 percent of observed cancers and about 19 percent of cancer deaths among Ohio women. In 1994 nearly 7,000 women will be diagnosed with breast cancer in Ohio. Over 2,000 will die from the disease.

Using currently available data from The Ohio Cancer Incidence Surveillance System,[2] we can further examine the problem of breast cancer by region of the state, and even county by county. It should be noted that these data do not currently include those cases diagnosed among Ohio residents receiving their diagnoses or treatment outside Ohio. Since this hearing is focused on breast cancer in Northeast Ohio, allow me to make a few comparisons of breast cancer incidence rates for Northeastern Ohio, the state as a whole, and the nation.

In 1992, the Ohio Cancer Incidence Surveillance System recorded 6,978 Ohio women newly diagnosed with breast cancer. This results in an age-adjusted rate of 101.4 per 100,000 women. This rate is slightly lower than the United States rate of 108.8 per 100,000 women. During 1992, there were 3,099 cases of breast cancer diagnosed among women in the 22 county region of Northeast Ohio. This results in a rate of 104.0 per 100,000 women. [Figure1: Breast Cancer Age-Adjusted Incidence Rates per 100,000.]

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[1] Centers for Disease Control. Chronic Disease Reports: Deaths from Breast Cancer Among Women - United States, 1986. Morbidity and Mortality Weekly Report 38:565-69, 1989.

[2] The Ohio Cancer Incidence Surveillance System (OCISS) was established in 1992, pursuant to H.B.213, sponsored by Ohio State legislator, Rep. Katherine Walsh.

This Northeast Ohio regional rate is slightly higher than the Ohio rate, but lower than the estimated rate for the nation. The individual county rates show a wide range of variation from a low of 63.6 per 100,000 women in Coshocton County to a high of 125.8 per 100,000 women in Medina County. Here in Lorain County the rate was 104.7 per 100,000 women, while in nearby Cuyahoga and Lake Counties, the rates were 116.8 and 117.7 per 100,000 women, respectively. [Figure 2: Direct Age-Adjusted Breast Cancer Incidence Rates per 100,000 Among Women in Ohio, Northeast Ohio, and Northeast Ohio Counties, 1992, and the United States.]

We know that the risk of breast cancer for a woman increases with age. For example, at age 30, a woman has a risk of 1 in 2,525 of developing breast cancer. At age 60, this risk increases to 1 in 24, while at age 85, this risk increases to 1 in 9. [Figure 3: Risk of a Woman Developing Breast Cancer.]

The age-specific rates for women in Northeast Ohio show how the risk for breast cancer rises with increasing age. For example, the rate for women age 30 - 34 years is 22.0 per 100,000 women, while for women age 60 - 64 years, the rate increases to 287.4 per 100,000 women. For the age group 80 - 84 years, the rate is 439.2 per 100,000 women. While this relationship between rate of breast cancer and increasing age is striking, it is important to note that the age-specific rates for Ohio and Northeast Ohio are comparable to the rates for the United States across all age groups. [Figure 4: Breast Cancer Age-Specific Incidence Rates per 100,000.]

What do we know about preventing breast cancer?

There are no known ways to prevent breast cancer. We know that certain risk factors may play a role in the development of the disease, but we cannot pinpoint a direct relationship between any woman's breast cancer and a single cause. [Figure 5: Factors Contributing to a Woman's Risk for Development of Breast Cancer.]

We know that the risk for breast cancer increases as a woman ages; the Ohio Department of Health data confirm this. Moreover, women with mothers, aunts, and sisters who have had breast cancer are also at greater risk for the disease; thus heredity plays a role. Interestingly, certain unhealthy behaviors, which are controllable by the individual, account for the most increased risk for breast cancer. These include eating a high fat diet, lack of exercise, tobacco smoking and excessive alcohol consumption. In addition, other factors such as delayed child bearing, late onset of menstruation and early menopause are also associated with increased risk.

Without the means to effectively control all known risk factors, this information suggests that if we are to combat breast cancer, we must focus our efforts on the early detection of the disease and the reduction of mortality where possible. The earlier a breast cancer is diagnosed, the more likely the disease is treatable and death preventable. The survival rate is over 95% when breast cancer is diagnosed at an early stage.

Tools for early diagnosis include breast self-examination, where a woman is trained to regularly examine her breasts for signs of cancer; clinical breast examination, where a physician or other trained health professional examines a woman's breast at scheduled intervals; and mammography, where a woman's breasts are radiologically screened for signs of cancer. The Ohio Department of Health recommends that women in Ohio follow the American Cancer Society's breast cancer early detection guidelines. Through the combined practice of monthly breast self exam, clinical breast exam by a trained health professional and screening mammography, death due to breast cancer can be reduced by as much as 30%. This early detection plan saves lives.

Despite these recommendations, however, numerous studies reveal that breast clinical examination and mammography are underused. Patterns of underuse appear to be most severe among certain socio-demographic groups: rural populations, the socioeconomically disadvantaged, the elderly, and ethnic and racial minorities. In Ohio, only 50% of women over 40 years of age are meeting the American Cancer Society and Ohio Department of Health mammography screening guidelines. This percentage decreases significantly with increasing age, and decreasing income and education level. [Figure 6: American Cancer Society and Ohio Department of Health Breast Cancer Early Detection Guidelines.]

Ohio women give many reasons for not getting mammograms on schedule. One of the major reasons cited is that their health care providers do not tell them a mammogram is needed. A significant number of women report that they did not know a mammogram was needed. Other reasons include the fear of pain, inconvenience, inability to pay for the mammogram, and simply the uncertainty of how to access the health care system for this effective preventive health measure. In addition, many women are so afraid they will be diagnosed with breast cancer, that they just don't want to have the screening tests to find out. All of these "reasons" point to a lack of accurate information on the part of both women and their health care providers.

It is clear that if Ohioans are going to make progress to reduce breast cancer morbidity and mortality, we must increase public awareness of the disease, instruct women and their health care providers in early detection methods and screening practices, assure that mammography screenings meet quality standards, and improve access to the health care services women need.

What is the Ohio Department of Health doing to combat breast cancer in Ohio?

While Ohio does experience a significant burden from breast cancer, it is also fortunate to have many important components in place to combat breast cancer, both within the public and private health care systems, and among numerous voluntary and community based organizations.

The first component of our attack on cancer in general, and breast cancer in particular, comes in the form of Ohio's first statewide cancer plan, The Ohio Cancer Plan 1992 - 2000. The plan was developed in cooperation with numerous providers and community leaders in the field of cancer throughout the state. This plan establishes reasonable cancer reduction goals for the year 2000 relative to national goals and current trends. With respect to breast cancer, the plan concentrates on early detection, improved access to affordable mammography screening, quality assurance of mammography screening and cancer surveillance to more effectively target intervention strategies. The Ohio Department of Health is already moving ahead in each of these areas.

I am pleased to report that the Ohio Department of Health has received $2.7 million this year from the federal Centers for Disease Control and Prevention (CDC) to implement a comprehensive project addressing breast and cervical cancer in Ohio. The Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354, authorizes the establishment of this project, administered by the Centers for Disease Control and Prevention in partnership with state agencies such as the Ohio Department of Health.

This project promotes educational programming for Ohio's women and their families, and also includes a systematic component of professional education. I stressed to you earlier the importance of the provider making appropriate mammography screening recommendations. In addition, the project also requires monitoring of mammography quality assurance, continued surveillance and evaluation of progress in meeting objectives to increase awareness and reduce mortality.

A major component of the Ohio Department of Health project establishes regional projects to reimburse providers for the delivery of early detection services to women meeting certain age and financial criteria. Over 75% of the women enrolled are required to be over 50 years of age. Currently, the financial eligibility includes women at or below 200% of the federal poverty level.

The vast majority of women enrolled in the projects will receive good news that their screening tests are normal. For women with abnormal screening results, case management assistance for follow-up diagnostic services and treatment will be provided. All women participating will be contacted annually to arrange for their next screening visit. Four multi-county pilot projects received funding in January 1994. The remaining projects will receive funding beginning September 1, making these services and associated educational programs available to women statewide before the end of the year. To facilitate further expansion of the project, the Ohio Department of Health has requested an additional $1.8 million in funding for this project in its second year. [Figure 7 (Map): Breast and Cervical Cancer Project Regions.]

One of the original pilot projects is here in northeast Ohio. The Cuyahoga County Board of Health has worked quickly and effectively to collaborate with providers and community agencies to put their project in place. Within four months of receiving their funding, the Cuyahoga County Health Department was providing services to women in need. They should be commended for their commitment and for their ability to implement this complex, comprehensive project so quickly. These services are now beginning to be made available to eligible women throughout the five-county region, which includes Lorain County.

Another activity we are involved with is cancer surveillance. The Ohio Cancer Incidence Surveillance System (OCISS) is a population based cancer incidence reporting system that collects epidemiologic information on cases of cancer diagnosed or treated in Ohio. The OCISS is a valuable tool in identifying populations at high risk of developing various types of cancer. This is a critical first step in the design and later evaluation of intervention strategies for cancer prevention and control. With data collected and monitored through the OCISS, we will be able to assess cancer incidence trends and better target cancer intervention strategies.

The Ohio Department of Health also supported recent legislation, House Bill 142, which will reduce the financial barrier to mammography for many Ohio women. The new law requires insurance companies to offer coverage for mammograms. Many insurance plans, including Medicaid and Medicare, now cover screening mammography.

The Ohio Department of Health also oversees the licensure of mammography facilities. Ohio has over 200 accredited mammography facilities throughout Ohio, including over a dozen mobile units. The quality of mammography services has improved dramatically over the past few years, with several new technologies providing more sensitive and specific screening and diagnostic tests. Federal legislation has been strengthened by the Mammography Quality Standards Act of 1992, Public Law 102-539, which will be implemented this fall to further assure the quality of all mammography services.

Another major component worth noting is the recent creation of the Office of Women's Health Initiatives within the Ohio Department of Health. This Office will serve to further assess and document existing programming and funding related to women's health issues. The Office will coordinate programs across all levels of government to improve the status of women's health, including the reduction of breast cancer mortality. And finally, the Office of Women's Health Initiatives will work to secure additional financial resources for projects serving Ohio's women.

What can women do for themselves to reduce their risk for breast cancer?

To a large extent, women in Ohio can reduce their own risk for breast cancer by modifying personal behaviors that lead to many poor health conditions: eliminating smoking, eating a balanced low-fat diet, and exercising. Women should also practice monthly self-breast examinations, and they should quickly report suspicious breast lumps or breast conditions to their physicians or health care providers. Women should know the recommended schedule for mammography screenings and make certain mammograms are obtained. Women with high risk for breast cancer should work with their physicians for suitable screening intervals. The key here is education and personal responsibility.

Conclusion

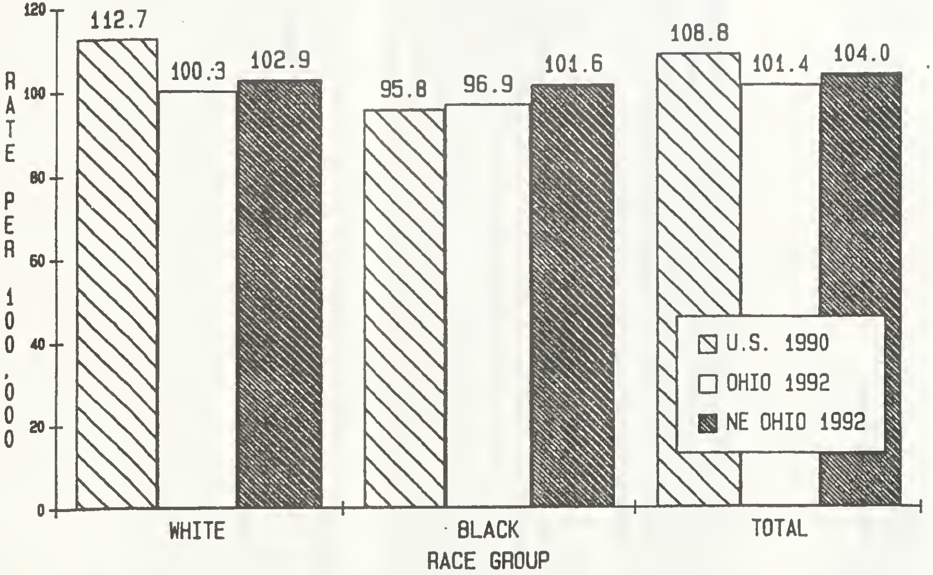
The data we presented today suggest that breast cancer rates in Ohio are comparable to rates for the United States across all age groups. In Northeastern Ohio, the rates follow a similar pattern, although there is some variation when rates are examined by individual county. More important than these numbers, however, are the activities the Ohio Department of Health is undertaking to reduce unnecessary breast cancer deaths. Our Ohio Cancer Plan lays out a plan of action emphasizing education, quality assurance and early detection. Soon, our CDC-funded projects for early detection of breast and cervical cancer will be underway throughout the state. Moreover, we will continue to learn more about breast cancer incidence as more data are collected through the Ohio Cancer Incidence Surveillance System. We will continue to monitor the quality of mammography screening units around the state, and we'll continue to promote regular self breast exams, clinical breast exams and mammograms for women based on our recommended guidelines. Our new Office of Women's Health Initiatives will promote education for women about the importance of early detection of breast cancer.

I conclude this testimony by acknowledging the tireless efforts of many other organizations and agencies throughout Ohio toward reducing breast cancer morbidity and mortality. These include the American Cancer Society, Ohio Division, and their county units; the Ohio Council of YWCAs; the American Association of Retired Persons; the Susan G. Komen Foundation; the Ohio Commission on Minority Health; the Ohio State Medical Association and numerous others. I am optimistic that the Ohio Department of Health, with our many partners statewide, can meet our state's year 2000 breast cancer reduction goals. Many of the pieces are already in place. The Ohio Department of Health has a plan, and we are moving ahead to meet the plan's established goals.

I urge you to continue to support funding for breast cancer early detection and treatment at every level and at every opportunity. I also urge you to promote awareness of the value of early detection for breast cancer, not only among your constituents and their health care providers, but also among your colleagues in Congress. Thank you very much.

Figure 1

BREAST CANCER AGE ADJUSTED
INCIDENCE RATES PER 100,000



Source: (1) Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases, The Ohio Department of Health, 1994. (2) Miller BA, Ries LAG, Hankey BF, Harras A, Devesa SS, Edwards BK (eds). SEER Cancer Statistics Review: 1973-1990, National Cancer Institute. NIH Pub. No. 93-2789, 1993.

Figure 2

DIRECT AGE-ADJUSTED BREAST CANCER INCIDENCE RATES PER 100,000 AMONG WOMEN IN OHIO, NORTHEAST OHIO, AND NORTHEAST OHIO COUNTIES, 1992 AND COMPARISON TO THE UNITED STATES[1]

	NUMBER OF CASES	RATE PER 100,000 WOMEN
OHIO	6,978	101.4
NORTHEAST OHIO	3,099	104.0
Northeast Ohio Counties		
Ashland	28	92.4
Ashtabula	66	101.6
Carroll	15	91.6
Columbiana	66	90.6
Coshocton	17	63.6
Cuyahoga	1,179	116.8
Geauga	46	96.0
Harrison	12	106.6
Holmes	13	77.9
Jefferson	64	111.5
Knox	27	85.5
Lake	163	117.7
Lorain	167	104.7
Mahoning	164	82.3
Medina	85	125.8
Portage	69	93.6
Richland	67	79.5
Stark	284	112.2
Summit	298	88.5
Trumbull	156	100.3
Tuscarawas	61	101.8
Wayne	52	91.0
United States[2]	72,867	108.8

[1] Source: Ohio Cancer Incidence Surveillance System; Cancer Epidemiology, Prevention and Control Program, Bureau of Chronic Diseases, Ohio Department of Health, 1994.

[2] United States rate is the estimated average annual breast cancer incidence rate from the population based registries of the National Cancer Institute for the years 1985-1989. Source: Miller BA, Ries LAG, Hankey BF, Harras A, Devesa SS, Edwards BK (Editors). SEER Cancer Statistics Review 1973-1990, National Cancer Institute, NIH Publication No. 93-2789, 1993.
bcic.tab/ede

Figure 3

RISK OF A WOMAN DEVELOPING BREAST CANCER[1,2,3]	
Age (Years)	Risk
25	one in 19,608
30	one in 2,525
35	one in 622
40	one in 217
45	one in 93
50	one in 50
55	one in 33
60	one in 24
65	one in 17
70	one in 14
75	one in 11
80	one in 10
85	one in 9

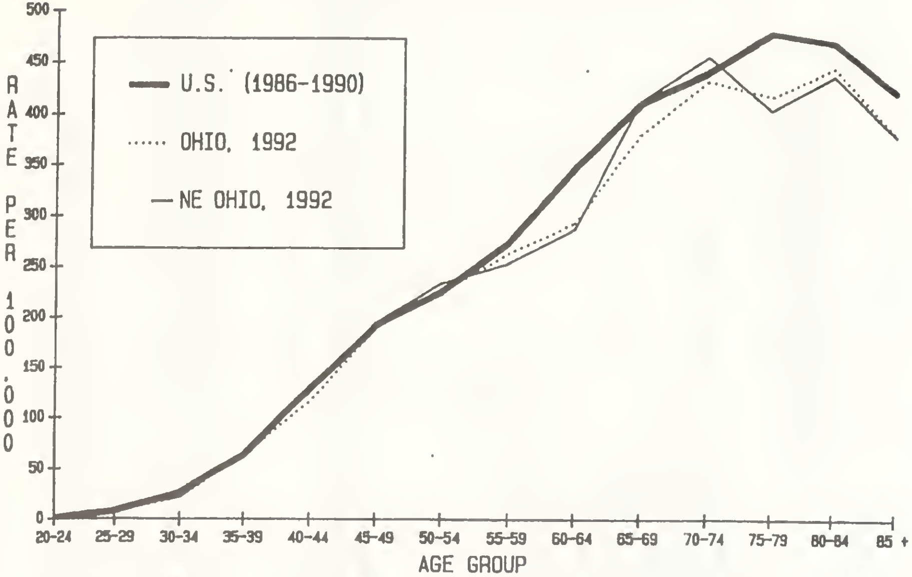
[1] Table by Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases, Ohio Department of Health, 1994

[2] Data from Surveillance, Epidemiology, and End Results Program (SEER), National Cancer Institute.

[3] Source: Marshall E. Science 259:618-621, 1993.

Figure 4

BREAST CANCER AGE SPECIFIC
INCIDENCE RATES PER 100,000



Source: (1) Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases, The Ohio Department of Health, 1994. (2) Miller BA, Ries LAG, Hankey BF, Harras A, Devesa SS, Edwards BK (eds). SEER Cancer Statistics Review: 1973-1990, National Cancer Institute. NIH Pub. No. 93-2789, 1993.

Figure 5

Factors Contributing to a Woman's Risk for Development of Breast Cancer

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- Increasing Age
- History of Breast Cancer in a Female Relative
- Nulliparity (having no children)
- Delayed Child Bearing
- Early Menstruation
- Late Menopause
- High Fat Diet
- Lack of Exercise
- Tobacco Smoking
- Excessive Alcohol Consumption

Source: Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases; The Ohio Department of Health, 1994.

Figure 6

American Cancer Society/Ohio Department of Health Breast Cancer Early Detection Guidelines[1,2]

Women age 20-39 years:
- Practive monthly breast self-examinations
- Clinical physical examination of the breast every three years

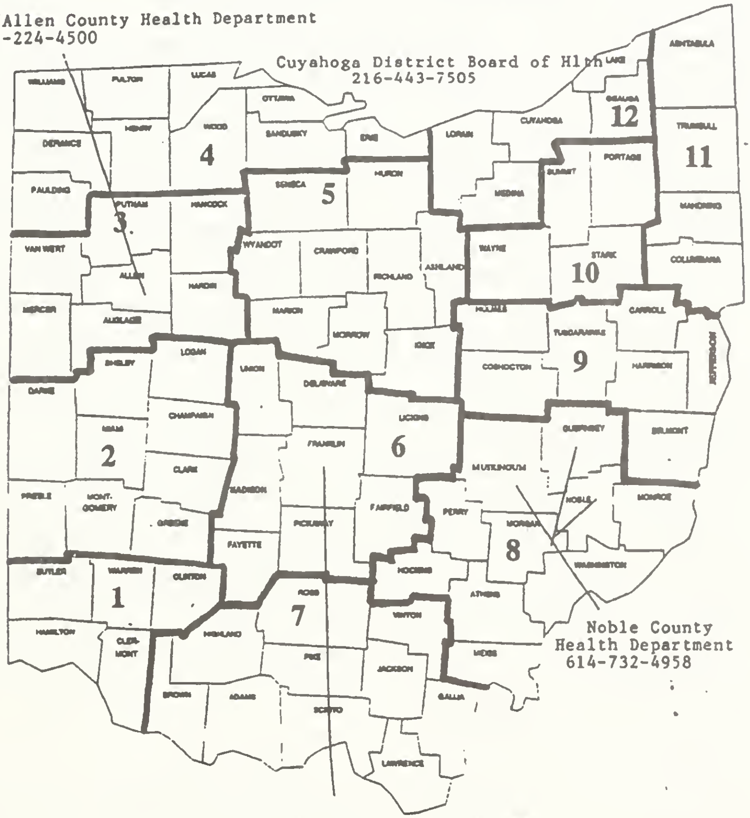
Women age 40-49 years:
- Practice monthly breast self-examinations
- Have a screening mammogram by the age of 40
- Get a screening mammogram every 1-2 years
- Clinical physical examination of the breast every year

Women age 50 years and older
- Practice monthly breast self-examinations
- Clinical physical examination of the breasts every year
- Have a screening mammogram every year

[1] Source: American Cancer Society/Ohio Department of Health, 1992.
[2] Table by Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases; The Ohio Department of Health, 1994.

Figure 7

BREAST AND CERVICAL CANCER PROJECT REGIONS


Lima/Allen County Health Department
419-224-4500

Cuyahoga District Board of Hlth
216-443-7505

Noble County
Health Department
614-732-4958

Columbus City Health Department
614-645-1836

Map by Breast and Cervical Cancer Early Detection Project; Cancer Epidemiology, Prevention and Control Program; Bureau of Chronic Diseases, Ohio Department of Health, 1994.

Mr. WAXMAN. Ms. Chilcote.

STATEMENT OF NANCY CHILCOTE

Ms. CHILCOTE. My name is Nancy Chilcote and I am a breast cancer survivor, and I find it kind of humorous or maybe interesting that I meet none of those 10 risk factors. Yet at the age of 31, my husband found a tumor in my right breast. So it is clear we really do not know what the risk factors are yet.

My tumor was 2.6 centimeters, which I was told by my surgeon meant that it was 8 to 10 years old, which meant that my tumor started growing when I was in college or law school. I did not grow up in northeast Ohio, I grew up in Bay County, Mich. And although it was quite a shock to have a mastectomy at a young age, I have to admit that I really did not get involved in what I consider my newest career as breast cancer advocacte until I read about a year and a half ago that a researcher had connected high levels of a pesticide in women's blood with increased risk of breast cancer. This was a DDT metabolite. DDT is a type of pesticide, which although is no longer used in the United States, it is still manufactured in the United States to be sold to places like Mexico and Central America where we buy lots of our fruits and vegetables.

At that time, I became a little alarmed. I am an environmental lawyer and had some contacts with the U.S. EPA and spoke with someone involved with a farm study. They are trying to study farmers and cancer rates to see if perhaps some of the pesticides used on farms increase cancer rates, I was told that since I lived in Michigan—and I knew this—I was exposed to a PBB chemical that was in all the cows. There was a mixup and they fed cows a fire retardant instead of a vitamin mixture, and the company tried to hide it and it was not until it was all over the lower part of the State that it became public knowledge. And so he said you still have that in your breast tissue, that is unless you had a child or you nursed any children. At that point, I became very angry because I have two children and I nursed both of them, and I have them with me here today.

So now you do not have it in your breast tissue, you have passed most of it on to your children since it is carried in your fat tissue, you pass it on in your breast milk. I have subsequently found out that there apparently is a higher rate of breast cancer in Michigan, and interestingly enough, a higher rate of testicular cancer in sons of women that had high doses of PBB. I have alerted my pediatrician that my son may be at high risk for testicular cancer and obviously my daughter is at high risk, having a mother diagnosed at the age of 31, for breast cancer.

I also have subsequently found out, within the last 12 months, that Saginaw Bay and Saginaw River and the county I grew up in has been ranked as a tie for the number one contaminated spot in the State of Michigan, tying with a large Superfund site, because Dow Chemical produced dioxin for use in Agent Orange during the Vietnam War and that was just upstream, up wind and our water supply came from the Saginaw River and Saginaw Bay.

Whether that has anything to do with the fact that I was diagnosed with breast cancer at the age of 31, I am sure I will never know. But when I read the study, I had to call and find out more information, because I just have always thought that maybe that was why I got breast cancer.

I subsequently have spoken with the person who wrote the study—it was published in April of 1993—he is from the Harvard School of Public Health and he said this should be a wake-up call. The women of this country should be screaming what have you done to our food supply, what have you done to our water, what have you done to our air. Is it really causing us to have breast cancer, because he thinks there is a relationship between the type of chemical which accumulates in breast tissue. PCB and DDT and dioxin are just examples. They are chlorinated organics called organochlorines.

And it was kind of interesting, because this was 1993 and the researcher from the U.S. EPA told me the same thing, only he sent me an article he published in 1983, 10 years earlier, trying to urge our government to look at the possible connection between accumulating pesticides in breast tissue and breast cancer. And I decided at that moment that since nothing had been done from 1983 to 1993, that I only had about 10 years left before my daughter would be of the age that she could perhaps get breast cancer—she is 7, so 10 years from now she would be 17 and people are diagnosed about the age of 18.

So I decided to get very involved, and at that point I got involved with the National Breast Cancer Coalition. I worked in Ohio last summer to gather signatures and we took 2.8 million signatures to the President last fall, asking for a national strategy to end the epidemic. We were tired of getting no answers to our questions, such as why are more women getting breast cancer now than used to be. I think you heard someone testify earlier when she was diagnosed the statistics were 1 in 17; when I was diagnosed, it was 1 in 11. It is now 1 in 9. I have heard 1 in 8. I wonder what it is going to be when my daughter gets breasts. Is it going to be 1 in 5; is it going to be 1 in 4? Why is it that it is increasing so much in our population? Why is it increasing so much in women under 40, which is very critical because mammography, although it is wonderful, does not work as well for people with dense breasts. Our tumors are not seen in mammogram machines. It is not a panacea. There are some types of tumors that are never seen by mammograms and there are some types of breasts that mammograms do not work well for. Younger women generally have denser breasts and mammograms do not work well for them. It is particularly critical I think that the incidence rate seems to be rising in that part of the population for which we have no very good early detection method.

Why are there pockets of breast cancer high in some areas? Long Island is the highest; Cleveland, the metropolitan area around Cleveland—Cleveland, Lorain, Medina Lake—are higher than the national average. Why is that? Is it because of Lake Erie? That is such a frightening thought. The fish in Lake Erie have high levels of DDT and PCB. The shore birds that eat those fish are born mutated with bills that do not cross. The mink die, the gulls die. There was a recent article in the Plain-Dealer saying DDT and PCB levels are decreasing in the Great Lakes except of course in the islands in Lake Erie where they are just the same, which does not give me a whole lot of comfort for my daughter growing up in Cleveland. There are fish advisories. I do not eat the fish—but our Governor does not want to publish them and wants to weaken them because he does not want to hurt the fishing industry. Does that mean more women and more of our daughters will be getting breast cancer because they do not know you should not be eating the fish out of Lake Erie, just in case this possible link between pesticides and breast cancer is a reality.

I would like an answer as to why was Armand Hammer, who was chairman of Occidental Chemical, on the National Cancer Advisory Board—I just have to ask, where were his interests? Were they with me and my daughter or were they with his company that created Love Canal?

I think there should be more women or consumers who have had breast cancer involved in making these decisions. How can someone possibly know what it is like to lose your breast unless you have lost it. And I know in the recent controversy over mastectomies versus lumpectomies, people screamed that they were not told about this data inconsistency when it was first found out, but the people making the decision as to should we tell her, is it important or is it not important, had never had a lumpectomy or a mastectomy. How could they possibly tell what all the women in this country would feel like when they were told, oops, there was a little bit of data inconsistencies, but we still think it is OK that you all had lumpectomies. I think there need to be people who have had breast cancer involved in some decision-making at the Federal Government level.

I would like to know why there is not an earlier detection test, like a blood test, like there is for prostate cancer. And I would like to know what we are going to do with health care reform. We know that the survival rate at HMO hospitals for people that are diagnosed not early enough is 20 percent versus 60 percent at major metropolitan hospitals. There has been a study released out of Los Angeles. If you are in an HMO hospital, your survival rate for breast cancer is 20 percent, versus if you are in a major metropolitan hospital, it is 60 percent. How can we send our Americans into a health care plan when we are going to be killing them? I would like an answer for that.

I would also like to emphasize that we need a national plan. We cannot do this in dribs and drabs. We cannot have a hospital in some Congressman's district getting the breast cancer funding through pork barrel politics; we have to have a national strategy. We cannot drib and drab away the next 10 years because I want this disease cured by the time my daughter is old enough to get it.

I know there has been a national blueprint created through a Department of Defense study and that has been funded partially—there was a $210 million program funded through the Department of Defense—the Army has women too. And they created a blueprint as to where we need research, and asked for research grants and received 1,200 meritorious research grants and were only able to fund 400. We are asking, as long as it has gone this far, we have created the blueprint, we have gotten the RFP's, we have gotten the grant proposals, let us complete that project. I think we really need a national focus if we are going to solve this epidemic.

And I cannot emphasize enough that we need more clinical trials and more research. We do not get answers otherwise. And I listened to someone testify earlier about the small number of women involved in clinical studies.

There are no easy answers when you are diagnosed with breast cancer, there are just questions. I went to four different hospitals, I got four different suggested treatment options before anybody had ever cut my skin. Nobody knows how to treat breast cancer. The mortality rate—yes, you live 5 years, but the mortality rate overall is still the same as it was 50 years ago. You may live 10 years when you are diagnosed with breast cancer, but still about 40 percent of women die from breast cancer and that is what it was 50 years ago. We have not touched that rate. We keep them alive a little bit longer, but they are still dying of breast cancer. No one knows what to do. We need more clinical trials to give us at least some answers or some glimmer of answers so when women are making decisions—do I do lumpectomy, do I do mastectomy, do I do chemo, do I do intensive chemo, long-term chemo—there are no answers except well there has been this clinical trial that has shown this and there has been this clinical trial that has shown that. That is the only answer that seems to be out there.

So I am hoping that through this hearing, we are going to have a full court press and that our Nation is going to take women's health very, very seriously. It is striking a very sensitive part of our population. It is the leading killer in women age 34 to 54.

And I just want to mention in closing that this pin I wear is in recognition of the close to 50,000 Americans that will die this year from breast cancer.

Thank you.

Mr. WAXMAN. Thank you very much, Ms. Chilcote.

[The prepared statement of Ms. Chilcote follows:]

Testimony of Nancy Chilcote

Hello, my name is Nancy Chilcote. I am a breast cancer survivor and a breast cancer activist. I am here today speaking as a member of the National Breast Cancer Coalition. I want to thank you for giving me this opportunity to speak. Congressman Brown and Congressman Waxman, clearly you both are friends. Your support for NBCC goals and priorities is known and appreciated. Your convening this gathering today is in itself a statement of your commitment to women's health.

The National Breast Cancer Coalition was founded in 1991. We have over 350 member organizations and speak on behalf of men, women and children across the country. In 1992 we organized the "Do the Write thing Campaign" that sent over 670,000 letters to the President and members of Congress. In 1993 we presented 2.6 million signatures in support of a National Action Plan on Breast Cancer to President Clinton. We are fighting for the eradication of breast cancer. Daily we work for increased research funding, access to screening, diagnosis and treatment for all women regardless of age, race or class and we work to increase the influence of women living with breast cancer in all policy decisions as they relate to breast cancer.

In Ohio, The Women's Health Information Network of Canfield serves as the NBCC state coordinator, distributing educational materials and working toward the three goals I have enumerated. I assist both the National and The Women's Health Information Network by working on those issues in Cleveland and developing the advocacy data base we use to alert our membership when important issues are before the legislature.

While our agenda is broad as we work with government on implementation of the National Action Plan on Breast Cancer, today I would like to focus on three very important priorities.

First, in 1992, the Congress established the Dept. of Defense Breast Cancer Research Program. That program was funded with 210 million dollars to be spent over two years. In 1993 the Congress adopted continuation language and appropriated another 25 million dollars into the program. This is an excellent program and we believe it must continue. It must continue with meaningful funding so that research continues. When grant applications were requested the Department of Army received 3000 proposals. A rigorous system of peer review determined that 1200 of those proposals merited funding. The 210 million appropriated could only fund 400 of those 1200 meritorious projects. We want to encourage young scientists to enter the research fields. We want to encourage experienced researchers to work cooperatively and in multi-discipline groups. The Dept. of Defense Breast Cancer program does that. It can only continue to do that, if it is continued with sufficient funds.

We also believe health care reform is an essential component to the eradication of breast cancer. I stated that our second goal is access for all women to first rate screening, diagnosis and treatment of breast cancer. Today, we know we could reduce breast cancer mortality by 30% in women over 50 if they all had regular mammograms. No one knows how to prevent breast cancer. No one knows how to cure everyone who gets it, or which women treated will be cured. We do know that early detection significantly improves your chances of survival. Mammography is our best early detector to date. We also know that rural, minority and poor women are more likely to die of breast cancer. They do not have ready access to the screening, diagnosis and treatments that could save their lives. Today, there is one national program that addresses the needs to those rural, minority and poor women with respect to screening. It is the CDC Breast and Cervical Cancer Early Detection Program. But it funds screening only - and it is not yet available in every state. Universal health care coverage, through a health care reform program, in our judgement is they only way to address our goal of access to quality screening, diagnosis and treatment. Any new health care package must also end the pre-existing condition exemptions. Thousands of women with breast cancer can not change jobs or move because they would be unable to secure health insurance if they did so. Today women who have had a benign lump removed are often exempted from breast cancer coverage. And unfortunately- mammography does frequently yield false positives - that is reveals lumps that look suspicious and must be biopsied but happily prove to be benign. We tell women to be screened. We are diligent and careful in our follow up after screening and then a woman with a good result risks losing an important piece of health insurance.

Research, basic research and clinical trial research, hold the answers. No one can predict how long it will take to find useable answers and then translate those answers into treatment. We do know that clinical trials matter and that very few women are enrolled in those trials. Increased enrollment in increased numbers of trials running simultaneously could shorten the research time line. More researchers adequately funded to pursue their meritorious proposals could shorten the research time line. Through health care reform we hope we can strengthen our national system of clinical research: To include more doctors and their patients, to insure consumer participation in design, to insure accountability, to insure the financial viability of our research centers and the continuation of sufficient research funding.

In focusing on the DOD research program and health care reform, it is not my intention to discount in any way the high priority all members of the National Breast Cancer Coalition places on support for the National Cancer Institute. Continued support for research through NC is also essential. We would be doing ourselves a terrible disservice if we supported the DOD program, thinking we were increasing available funds and saw a decline in funding through NC. One of the issues often raised in discussion of NC funding is earmarking. Clearly, NBCC has been on record in support of earmarking. This does not mean we oppose basic research - we understand basic research is essential. This does not mean we believe that all breakthroughs in breast cancer will be made by breast cancer researchers, we know there is a great likelihood they will not, nor does it mean that breast cancer is the only cancer. But since our founding, and our call for earmarking, breast cancer research funds have increased four fold. This is not peter borrowing or stealing from paul - this is new money. New money to attract new researchers and to fund meritorious projects in the pipeline that would otherwise not be funded. When NBCC first came on the seen, many researchers viewed us with suspicion. It was thought we would invade the laboratories, control research, trivialize the enterprise. We have not. Instead a very strong partnership is being forged. We are allies not adversaries. We come to the table with different perspectives but with shared goals. Our mutual efforts are bringing about important change. And you, the members of Congress, before whom I speak are at the focus of this partnership. You are an essential element. It is because we are a democracy, because you are willing to listen to your constituents, because you can set priorities based on our needs - that the partnership is successful. It is because you respond that real change has come about. It was your votes that increased funding. It will be your votes that support continuation of the DOD research program. It will be your votes that bring universal coverage and health care reform. Thank you Congressman Brown for convening this hearing and giving the National Breast Cancer Coalition an opportunity to share our positions.

Mr. WAXMAN. Dr. Laing.

STATEMENT OF GLYNIS LAING

Ms. LAING. Good morning, Mr. Chairman and Sherrod Brown. On behalf of the Lorain County Regional Cancer Center at St. Joseph Hospital, we would like to welcome you to Lorain this morning.

My name is Dr. Glynis Laing. I am Program Manager of Cancer Services at St. Joseph Hospital, and I also serve as a board member for the Lorain County unit of the American Cancer Society.

You have already heard Dr. Somani's information this morning, and perhaps I could be of most help to you by telling you about the local efforts that are going on in Lorain County in terms of early detection and education and prevention of breast cancer.

When I went to our local hospital-based tumor registry, I realized that we had big pieces of our data that was missing. Our tumor registry happens to be set up so that it involves the three major hospitals in Lorain County: St. Joseph Hospital and Health Center, Lorain Community Hospital and EMH Regional Medical Center. But our registry only tracks patients that are diagnosed or treated at one of those three hospitals. Unfortunately, if a patient chooses to go to any other hospital, either within the county or out of the county, we do not know that they exist. One of the nice things is that with the OCISS system, the Ohio Cancer Incidence Surveillance System, we can now track that. That is a very new system. It was first started in 1992, but that should be a valuable resource to us to identify if we truly do have a problem in this particular region.

Lorain County has a very long history of a very positive collaboration among multiple agencies in terms of education, early detection and prevention education. Events like the Cancer Awareness Day are sponsored by the American Cancer Society at a local mall to educate the public on risk reduction. Screenings for breast, prostate, colon and skin cancer are held on a regular basis throughout the county. Disease specific support groups and survivors groups are conducted throughout this region, and ease of access for mammograms is facilitated because we offer late evening and weekend hours at multiple locations to obtain mammograms.

Lorain has a very diverse ethnic population, which kind of presents us with some interesting dilemmas on how to educate those women. But organizations such as the YWCA of Lorain and St. Joseph Hospital and the American Cancer Society and the Lorain City Health Department have been working together to receive grant funding to provide breast cancer screenings to the ethnic community in a culturally sensitive manner. We are also willing to do on-site coordination for other screening programs that funding is available for.

Our education and screening programs have not been restricted to traditional clinical types of settings. The Lorain County Regional Cancer Center has pioneered work site screenings here in this region in which we provide an educational component, a physical exam and mammography at a woman's place of employment. We have a Parish Nurse Program which has moved out into the churches in order to facilitate accessing people within their churches and moving them into an education and early detection phase. There is also a Community Health Advisory Council that involves representation from area social service agencies that addresses the issues of the overall health status of the people of Lorain County.

But in spite of all our efforts, or maybe even because of all our efforts, the community continues to be very concerned about the rate of cancer in this region. We have a cancer information line, which is a telephone line where people will call in for questions, and on a daily basis we receive calls like, "How can I prevent cancer?" "Where should I live to avoid exposure to cancer?" "Is there a problem in a certain geographic area?" And those are typically questions that we really do not have answers for. Perhaps a solid epidemiological study considering the factors impacting breast cancer in this area would be helpful in relieving anxiety of the people who reside here. Perhaps the Ohio Department of Health or NCI could be of assistance to people in this area in conducting that study.

My primary recommendation for assistance from you would center around reimbursement. At least under our current reimbursement system, and depending on what comes out of health care reform, it would be very helpful if reimbursement for educating and screening people on cancer risk reduction was available. Currently there is nothing available. And certainly the best thing you could currently do is to impact reimbursement for Medicare recipients in terms of mammography. Current reimbursement is once every 2 years and that discourages older women from seeking mammography at a time when they are at increased risk for the disease.

I do not agree with the National Cancer Institute's recommendations of not screening women under 50 years of age. I think it is imperative that women follow the American Cancer Society's guidelines for baseline mammography before age 40, a mammogram every 1 to 2 years until they are 50 and then yearly after that. Only with early detection can early treatment be possible.

And finally, reimbursement for both home care, hospice and long-term care services needs to be adequate so that we can continue to provide care to patients in non-traditional settings outside of the hospital walls.

I would like to thank members of the committee for hearing my testimony and I will be happy to answer any questions.

Mr. WAXMAN. Thank you very much for your testimony. I want to thank each of you. You have given us excellent testimony.

Dr. Somani, when you look at the breast cancer rates in Ohio, your chart showed that Ohio is pretty close to the national average. Yet, in fact, Ohio seems to be higher than the national average. It happens to be in the top 10 of the 50 States. Do you have an explanation for that?

Mr. SOMANI. We have looked at the information and we do not have any real explanation for why we are number nine. More recent data suggest we are number 11 in the Nation. We are also concerned about the fact that if you look at the national trend, you know, age dependent, we are within the same range as the national information.

But I have been analyzing this information more closely after OCISS data. We do have a slightly higher rate for pre-menopausal women in this part of the State. And that includes Cuyahoga County, Medina and to some extent Lorain and Lake County. We are not clear exactly why the incidence may be slightly higher than either Ohio or the national average. This is where we need to focus, looking at risk factors and this is why we would like to work with NCI, CDC and the local branch of the American Cancer Society to analyze cases such as yours and others, to define what may be the possible risk factors, because without knowing those, we cannot make a recommendation about the treatment and management plans.

Mr. WAXMAN. Dr. Laing, you talked about reimbursement for diagnostic services. Medicare now covers mammography and it is inconceivable to me that we have insurance companies that do not pay for diagnostic services. Certainly under the reform legislation before us in the Congress that would be covered everywhere. Is it widespread that private insurance does not pay for diagnosis?

Ms. LAING. Unfortunately, it really depends on the individual insurance policy. And what I find is that women really do not know what is covered and not covered and it seems that when they call they do not always get either consistent answers or they get different answers or that kind of thing. To have one standardized benefit, for instance all women covered for routine mammography, certainly would be helpful.

Mr. WAXMAN. Well I think it is helpful and essential, because we know so much about how early detection can make such a big difference. And then not to cover the test for early detection seems to me——

Ms. LAING. And certainly prevention is far less expensive than treatment.

Mr. WAXMAN. Absolutely.

Ms. Chilcote, you raised all the right questions and I want to thank you for them. Those are the things that we just cannot push aside and hope that maybe it is diet or some of these others things, which almost in some ways puts the burden on the woman to feel that she is responsible for getting this disease, as opposed to if there is a cancer causing environment, we ought to know about it and recognize that if industries have been polluting and causing these diseases, we have got to hold them responsible.

Ms. CHILCOTE. Yes, thank you. I think it is time we stopped blaming the victim, blaming the women, and saying we just did not eat enough broccoli and that is the problem.

Mr. WAXMAN. We do not want to minimize these things, but we do not want to over-emphasize them either. You are part of the National Breast Cancer Coalition and your organization in Washington has been tremendously effective. Congressman Brown and I have worked closely with them and some of the legislation that we now have on the books, that Dr. Somani says is now being endorsed here, are a result of the efforts of the Coalition working with us in Washington. The standards for mammography screening, the funds that are going to early detection, all of these things have been very helpful, but we have got to do more. So I thank you.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Laing, you have spoken about the calls you get on St. Joe's cancer information line from local residents who are concerned about all forms of cancer. Tell us, if you would, sort of the sentiment of those calls, and if you could make some comments about what you are hearing from people.

Ms. LAING. Probably what we hear most of all is a great deal of anxiety. I mean that is certainly the overriding emotion we hear over the phone. Our phones are answered by registered nurses who kind of screen calls and try to determine—if someone is describing symptoms to us or what we suspect could be a symptom, we refer that person back to their physician. But a lot of the things that we hear are is there a pocket in my area, with the recent media publicity about the hearing, I was just overwhelmed with the number of people calling and saying there are 6 women on my street, there are 10 women on my street. I mean, people who were able to grab numbers and say this seems abnormally high to me.

People are very concerned about what they can do to avoid any exposure, be it do they move from the area, do they eat broccoli, do they whatever. And that is, again, a real major concern. People are very concerned about how do I prevent this or what do I do to avoid the carcinogen exposure. Without a doubt, that is the overwhelming sentiment.

Mr. BROWN. You had talked about your sitting on St. Joe's tumor registry board. People in Lorain, particularly in this community but throughout the district, but particularly people in Lorain have approached me about the potential causes of cancer in northeast Ohio. Some talk about is it a problem with the lake or with the industry along the lake, of chemicals used in industrial processes, about electromagnetic fields. Do you—from your expertise and in your experience in listening to people and looking at what is happening at St. Joe's and looking particularly on the tumor registry board, do you have some thoughts on causes and beyond—Ms. Chilcote hit on a lot of things. Do you have some thoughts?

Ms. LAING. Unfortunately because the patients that we review on the tumor board are the ones diagnosed here, I see a skewed population because we have large contracts with industrial providers in this region. So I am not sure how much I am seeing because, you know, those patients come to us and how much of it is just by the roll of the dice, I don't know. Certainly alcohol consumption and tobacco are without a doubt a major cause. Now what you need to look at is when you combine tobacco and alcohol and then you add an environmental factor, do you get incremental risk when you add all those things together. And if you take any one of those factors out of the picture, does your risk drop.

We see a full range of cancer diagnoses, from breast to prostate to lungs to colons to everything.

Mr. BROWN. Ms. Chilcote, on Saturday, I met with about a dozen breast cancer survivors from northeast Ohio to talk about their concerns and their thoughts about this hearing, and particularly the issues related to breast cancer. One of the items that there was absolute unanimity on was they agreed that physicians, scientists, researchers and especially insurance companies simply do not take women seriously on the whole issue of breast cancer. What do we do about that?

Ms. CHILCOTE. Gosh, if you could come up with the answer to that, I will nominate you for a Nobel Prize—I am telling you.

Our society does not value women. Someone in my occupation as a lawyer would make ⅔ generally what a male makes, the same age, in any occupation. I think it is a centuries old problem and I am not exactly sure how to solve that problem. But the medical community has been primarily male. I think more women are coming into the medical community. That may help. But I can tell you that when I first felt my lump, a very renowned doctor said oh, you are too young to get breast cancer—a male physician. And that is a typical response, to dismiss the female's concern.

Women are just going to have to learn to be empowered and to speak up for themselves, and that is difficult too, because we have been taught to be sugar and spice and everything nice. And when you stand up and get angry, then that is not being very female.

So I hope you find the answer to that question.

Mr. BROWN. If you had an opportunity to fund a research project, Ms. Chilcote, in northeast Ohio, to really determine the causes of breast cancer, what would you consider, what would you like to see us do?

Ms. CHILCOTE. I did not come up with this myself, I got this from the epidemiologist at the U.S. EPA. His thought was that when people come into the hospital and have children, just sample their breast milk and then wait and see. I mean, do people with higher levels of pesticides—because breast milk is an indicator of how much pesticides you have in your body—end up with cancer. Does that correlate with higher rates of breast cancer? He maintains there was something that was done in Colorado quite a few years ago where they sampled breast milk and they froze it all, just to see what was there. Then you could go back and see now did any of those women get breast cancer. That is my first choice.

Thanks.

Mr. BROWN. Thank you.

Dr. Somani, partly in follow-up to not this question but the question I asked Ms. Chilcote a moment ago, a recent survey done by the New England Journal of Medicine demonstrated that women were twice as likely to have a Pap smear or a mammogram if their family doctor, their internist or general practitioner, whatever, was female. Then you also noted, and I mentioned, that the survey—that 50 percent or over 50 percent of women in Ohio over 40 said they did not receive a mammogram because their doctors simply did not recommend it. What is the State doing to improve the knowledge of physicians about women's health generally, but specifically about mammograms and breast cancer and other kinds of early detection?

Mr. SOMANI. Well as I mentioned in my testimony, we have been concerned about this issue for quite sometime. And as I indicated, we are taking a number of positive steps in this direction to solve these concerns and problems. Number one, we are concerned about the lack of availability of mammography, lack of insurance to pay for that. We have worked with the legislature to get a bill passed so that all new insurance policies, health care policies that are sold in Ohio must offer the appropriate reimbursement for mammography.

Mr. Brown. Well let me ask, what is the appropriate—is it frequent enough, is it specifically statutorily frequent enough and at an early enough age? And what is that?

Mr. Somani. Yes. The guidelines that we have incorporated are the ones that the Department of Health has recommended. Baseline at age 40, every 2 years thereafter, every year after age 50, so that these are the same guidelines as the American Cancer Society. We also said that the policy should include, if there is a strong family history and the doctor recommends that a woman undergo mammography, that should also be reimbursed.

Second, working with CDC, we have developed these educational programs and as I mentioned, there are four regionally funded programs to educate the public and women about the risk of breast cancer.

We are now working with the Ohio State Medical Society to address this issue in terms of education of physicians in general. As our own data showed, more than 50 percent of the physicians were not even making the recommendation. So that was a concern to me. We are now asking the Ohio State Medical Association and county medical societies to work with the practicing physicians and the community leaders to let the professionals also be trained. That is very important to look at prevention.

Mr. Brown. Describe—understanding the insurance coverage now and what that means for mammograms, there still was concern at this meeting on Saturday from women who have had mammograms and I have heard in many other places, just their lack of confidence of the sometimes poor quality of mammograms, sometimes that physicians are not reading them or physicians maybe perhaps are not reading them properly. What is part of the state plan with the upcoming licensure of mammogram facilities, what are you guaranteeing to make sure that there is more standardization, as I think Ms. Johnson said earlier, or Ms. Piccioni—Ms. Piccioni I guess said—and what are you doing to make sure that those mammograms will be read by physicians and that they are of better, more standard quality than they have perhaps been from time to time?

Mr. Somani. Well we also have been concerned about the quality of mammograms, as well as the quality of physicians who are interpreting the mammograms. We have been working with the FDA and we already have, through the Public Health Council, the rules to define the standards for all mammography places in the State. So far, we have looked at almost all county-wide, all the State-wide mammography operations and we have been now certifying them for both quality of the films that are taken as well as the standards for interpretation. We have used the same standards as the Federal FDA has established.

Mr. Brown. The numbers that the State Health Department has recently released that were brought forward in part because of the efforts of Representative Kate Walsh from this county, mention that the numbers show that Medina County is the highest—has the highest incidence of breast cancer in northeast Ohio, I believe in the State. Considering Medina is considered generally a rural county, some of the other issues we have talked about maybe do not play into that. How do you figure, why does that make sense that Medina County is so high?

Mr. SOMANI. Well this is one of those puzzling things that we, now with the establishment of OCISS—now that Representative Walsh is here, I can now thank her for sponsoring the bill—we now have data at least for 1 year and I believe that as we begin to establish more and more numbers, we will be concerned about what may be the underlying reasons for the high incidence of cancer in these four counties. We still are not clear. There are obviously a number of things to be looked at. We are analyzing the risk factors as well as any other factors that may be playing a role. I cannot say specifically what may be happening in Medina County to explain this information. But these are the numbers. We need to work together and only 2 weeks ago I signed a contract with Ohio State University to investigate all the risk factors in people who are with early diagnosis of breast cancer. So we will have a detailed analysis of possible risk factors. That may give us some information about what may be the cause.

Mr. BROWN. Last question for both Dr. Laing and Dr. Somani. As we have discussed, in preparing for this hearing and received information from people who have told their stories and people like Dr. Laing that have great expertise in this area, we have heard a lot about cancer rate generally. Many people have brought to my attention the serious concern about prostate cancer in northeast Ohio. Given the parallels, particularly hormonal links between prostate and breast cancer, should we be looking at both these diseases simultaneously, Dr. Laing and Dr. Somani?

Ms. LAING. Yes, I think that would be very appropriate.

Mr. SOMANI. Well the OCISS program does look at all cases of cancer, as they are newly diagnosed, so that we would be in a position to identify the same type of analysis for prostate cancer too. And we have been concerned about that also and I think—when the so-called mammography bill was being discussed—we heard that why should we not include paying for the screening for prostate cancer, and the bill does include that insurance companies should pay also for a screening for prostate cancer. So it is for both.

Mr. BROWN. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Brown.

Thank you very much for your testimony.

Our last set of witnesses is here to provide information on some of the Federal efforts designed to address the Nation's breast cancer epidemic. Testifying on behalf of the National Cancer Institute is Dr. Edward Sondik. Dr. Sondik serves as the Institute's acting Deputy Director. He is accompanied today by Dr. Iris Obrams, Chief of Extramural Projects and Programs at NCI and Director of the Long Island Breast Cancer Study Project.

Again, with St. Joseph Hospital and Health Center here in Lorain is Dr. Gabriel de Freitas. Finally, we will hear from Dr. Paul Schulte, an epidemiologist with the National Institute for Occupational Safety and Health, a branch of the Federal Centers for Disease Control and Prevention.

We want to welcome you to our hearing today, thank you very much for being here. Your prepared statements will be in the record without objection. What we would like to ask you to do is to summarize your statement in around 5 minutes.

I am going to have to apologize to this panel because my schedule is such that I have to catch an earlier flight back to Washington, DC. I will look forward to reviewing the testimony and the questions and answers with Congressman Brown at a later date, but I want to thank you for being here and I regret that I will not be here to hear your oral presentations.

We will start with you, Dr. Sondik.

STATEMENTS OF EDWARD J. SONDIK, ACTING DEPUTY DIRECTOR, NATIONAL CANCER INSTITUTE, ACCOMPANIED BY IRIS OBRAMS, CHIEF OF EXTRAMURAL PROGRAMS BRANCH; GABRIEL F. de FREITAS, SURGICAL ONCOLOGIST, ST. JOSEPH HOSPITAL AND HEALTH CENTER; AND PAUL SCHULTE, EPIDEMIOLOGIST, CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. SONDIK. Thank you very much and good morning, Chairman Waxman, Representative Brown. I am Edward Sondik, the acting Deputy Director of the National Cancer Institute. I am also the Deputy Director of the Division of Cancer Prevention and Control in the Institute, which focuses on many of the issues that have been discussed today. And I am pleased that with me today is Dr. Iris Obrams, Chief of the Extramural Programs Branch in NCI's Epidemiology and Biostatistics Program, and Director of the Long Island Breast Cancer Study Project, whose major focus is the causes of breast cancer.

If I could in my 5 minutes, I would like to give you just, I hope, a very brief overview of the NCI's approach to this problem, and then in the questions and answers, I would be happy to respond to a number of the issues that have come up. I want to thank, at the outset, the members of the previous panels who I think bring a great deal of wisdom, born from their clear, deep involvement in this problem. Many of the points made, I think, are right on target and if not being pursued, I believe they do need to be pursued.

The NCI is the lead Federal cancer research agency. We are one of the components of NIH, and we sponsor cancer research that covers the very broad spectrum of cancer from prevention through early detection and screening, diagnosis, treatment, outreach and education. We do not carry on this mission alone, by any means. We cooperate closely with other Federal agencies, State health departments, academia, industry, consumers and consumer groups. In the more extensive statement that we have submitted, we go into these programs in greater detail, and I hope you will have the opportunity to review it.

There is no question that breast cancer is perhaps the most formidable of the cancers that we face. I think it is the most formidable because despite the years of research on it, we still do not know what causes it. My reaction to the list of risk factors given is like that of some of the panelists. If you look at that list, you throw up your hands and you say, what can I do about it. One thing you certainly should do is not blame yourself if you do develop breast cancer. There is nothing that you can do about any of those risk factors. Those risk factors, though, are potent. They do explain between 30 and 70 percent of breast cancer. They do not explain 100 percent of it by any means, and we need to try to understand the remaining causes of this disease.

The incidence of the disease—that is, the number of new cases—has grown over the last 30 years at about 1 to 2 percent per year. But mortality over that period of time—and this is the positive part—has remained relatively constant. So at the least, we can say that we are keeping pace with this increase, but certainly that is "damning by faint praise" at best.

Different groups in the country fare differently with respect to breast cancer. I think this is important to point out. And in particular, the female African-American population over age 45 actually has a lower incidence of breast cancer, but the mortality is at least as high as it is among white women. And the reason for that is that their survival is considerably less. Overall 5-year survival from breast cancer is about 80 percent for white women. It is about 63 percent for black women. And that speaks in large part, I believe, to the interaction of that group with the health care system, and not addressing these cancers in time or perhaps appropriately in terms of quality care.

We have already heard about where Ohio ranks in these statistics and I completely agree with Dr. Somani. I will say, and I perhaps should not do this, because it is speculative, but we know that the mortality is relatively high in Ohio, yet the incidence is about average. One explanation for that has to do with when women are being diagnosed with the cancer. Perhaps they are coming in later. What it says is that the chances of dying from the cancer are higher in Ohio than they would be in another area. But these statistics need to be elaborated on, and I am most pleased that the cancer registry has been established in Ohio. My own personal view, and the view of the Institute, is that surveillance provides the bedrock, the foundation, for all of these efforts that allows us to evaluate these data and track them over time.

The other pieces of the foundation of this effort are basic research and investigator-initiated research. It is very, very important that the ideas come from the community and be translated back to and carried out in the community. Overall, the Institute spends half of its budget on investigator-initiated research. Also part of the national cancer research infrastructure is cancer centers, and Ohio has two cancer centers, one at Ohio State, a comprehensive center, and another at Case Western. Other components are the clinical cooperative groups which carry out treatment and prevention research throughout the country, and the Community Clinical Oncology Program or the CCOP's, which enable that research to be carried out throughout the country in smaller areas. There are a number of CCOP's in Ohio.

There are several key questions—and my time is running short, so I will just outline what they are. I think these are the most significant questions we can ask about breast cancer and they have all come up today.

First is what causes breast cancer. We are pursuing that actively. You are familiar with the tamoxifen trial that is underway. There is the Women's Health Initiative, which is conducted by NIH, focusing in large part for our purposes here today on the role of diet and the possibility that a low fat diet may prevent breast cancer. But we are looking at other agents and other causes through two major projects, and many other projects throughout this country and other countries, for that matter. One is on Long Island, headed by Dr. Obrams, which is developing methodology for testing factors that have not been able to be tested before, including potential factors that have not come up here today, such as aircraft emissions on the path flying into Kennedy Airport. We have another consortium of studies called the Northeast Study, that is focusing on again, these different factors in States in the northeast that have the highest rates of breast cancer. One component of those studies is concerned with nurses in Ohio and evaluating whether or not this group of nurses—that has now been studied for many years—has high risk.

The second major question is what can we do to prevent this disease, and I have mentioned a little bit of the research on that. Early detection is, as many have mentioned, our biggest hope at this point. This is the near-term solution. We can reduce mortality 30 to 35 percent, we know that, but 30 to 35 percent is much less than it should be, and we have an extensive program of research on new technologies, digital mammography, MRI, PET—in fact, one of the PET projects is here in Ohio.

In the treatment area, an extensive network of clinical trials is underway. There have been issues that have been mentioned concerning the NSABP and stopping those trials. I am happy to say that in fact those trials have been put back on track and they are open for recruitment in many of the sites, though not all at this point, and the tamoxifen trial, in particular, has started again to evaluate subjects. We are now up to around 11,000 of the planned 16,000 subjects in that primary prevention trial.

Finally, the fifth question I think is how do we translate these results into practical initiatives that people can take advantage of. And this, on the surface, should be an easy problem, but it turns out it is very difficult. I cannot explain why so many physicians do not recommend mammography to their patients. We have been talking about this, we have had materials, we have met with physicians, on and on, for the last decade. And yet, there are still physicians who simply will not respond to this. It requires not only the medical profession, talking to the medical profession. It requires, as well, those in the advocacy communities and in other institutions to work with their own physicians to get this point across, and to get it across to their own populations.

In closing, let me say that basic research, clinical trials and cancer centers are absolutely essential to this program. The in-depth studies in epidemiology that we have undertaken over the last several years, I think are going to make a significant contribution to the indemnification of risk factors, but I cannot tell you that there is any particular factor at this point that rises in prominence as the factor that causes breast cancer. If I could take 1 more minute, I was asked the other day, how is it we can get a man to the moon—this was by a Washington Post reporter—how is it we can get a man to the moon but somehow we have not been able to beat this disease. And I said that in 1960, when that effort started, we knew the physics of space. In 1970, when the major push on cancer started, the war on cancer, we may have thought we understood the physics of cancer or the biology of cancer. What we have learned is that we do not. But we have made tremendous progress, and I think that is the key. If we can understand the biology, we will then understand this disease and be able to deal with it. And we are working toward that.

Thank you very much.

Mr. BROWN. Thank you, Dr. Sondik.

Dr. Obrams, you are not making a statement, correct? You are for questions?

[Dr. Obrams shakes head negatively.]

[Testimony resumes on p. 101.]

[The prepared statement of Mr. Sondik follows:]

Statement of Edward J. Sondik, Ph.D.
National Cancer Institute

Good morning, Representative Brown. I am Edward J. Sondik, Acting Deputy Director of the National Cancer Institute (NCI). Accompanying me today is Dr. Iris Obrams, Chief, Extramural Programs Branch in NCI's Epidemiology and Biostatistics Program. We are pleased to present an overview of NCI efforts to combat breast cancer. The NCI supports studies covering all aspects of breast cancer research, including early detection and screening, diagnosis and prognosis, treatment, prevention and control, and outreach and education. Much of this research studies the role of numerous factors, including environmental and occupational exposures, in breast cancer development. The mission of NCI is to reduce suffering and death from cancer. Ultimately, NCI's goal is to prevent and cure this disease.

The NCI cannot conquer breast cancer alone. We need the specialized expertise of other Federal agencies, state health departments, academia, industry, consumers, and consumer groups, to move forward with our mission. In recognition of the formidable challenges we face, and the tremendous good-will among all sectors to work together, the Secretary of Health and Human Services (HHS), Donna Shalala, held a conference in December 1993 to develop recommendations for a national action plan on breast cancer. The conference embraced and involved the full spectrum of individuals, groups, and organizations concerned about breast cancer, and the invited participants worked together to compile a blueprint highlighting opportunities to advance and apply what we know, promote partnerships, and begin to design an operational strategy to conquer this devastating disease. Recommendations are directed toward other Federal agencies, non-Federal government and private sector organizations. Dr. Susan Blumenthal, Deputy Assistant Secretary for Women's Health, is coordinating the follow-up for the Secretary, and NCI is participating fully in areas related to its mission.

Collaborative efforts are already underway to study: possible environmental carcinogens and occupational risk factors; new and improved imaging technologies for early detection of cancer; dietary and hormonal factors; genetic aberrations and consequent molecular abnormalities; and gene therapy research. The NCI has organized an Inter-Agency Working Group on Breast and Gynecologic Cancer comprised of one or more representatives from most National Institutes of Health (NIH) Institutes and Centers, as well as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Department of the Army, and from Dr. Blumenthal's office. The group meets monthly and serves as an information clearinghouse and coordinating body for breast cancer activities, identifies current gaps in research, and advises NCI on how to most effectively close such gaps. The group has been designated as the coordinating body for member agencies with regard to the implementation of NCI's activities with respect to the national breast cancer action plan. The National Institute of Environmental Health Sciences (NIEHS), in conjunction with NCI, has developed new centers for the study of environmental and occupational exposures.

STATISTICS

Cancer is a devastating problem for Americans. In 1994, over 1.2 million Americans are expected to be diagnosed with cancer, and approximately 538,000 deaths are anticipated. There has been a slow but steady rise in the cancer mortality rate in the United States (U.S.) in the last 50 years, with the major cause of this increase being lung cancer. Lung cancer is the number one cancer killer of men and women, taking approximately 153,000 lives this year. Although the incidence rate for this cancer has declined in men, it continues to increase in women, and will kill 13,000 more women than will breast cancer this year. Lung cancer is largely preventable, since smoking is the leading cause of this disease. This is a broad societal issue that cannot be solved by scientific research alone.

Breast cancer is the second leading cause of cancer death among women and the most common cause of death from any cause in women aged 40-44. In 1994, 182,000 new cases of breast cancer in women will be diagnosed, and 46,000 women will die from the disease. Since 1973, breast cancer incidence rates, i.e., the number of new cases per 100,000 individuals per year, have increased 1.7 percent a year. Since 1987, breast cancer incidence fortunately has reached a plateau or slightly decreased. Some of the overall increase in incidence is attributed to early detection; some is less well understood.

More than 47 percent of newly diagnosed cases of breast cancer in 1994 will occur in women over age 65. The impact of cancer on minority and underserved populations is disproportionately great. This is certainly shown in breast cancer mortality rates. Data have shown that while the **incidence** rates for breast cancer in African American women are lower than those for white women, the **mortality** rates of African American women are higher, reflecting much lower survival rates and a lower proportion of cases detected at the earliest stages of the disease. The fact that increases have been seen for younger as well as older women supports the notion that new or changing etiologic factors may be involved. Of interest is how risk factors may differentially affect Caucasian and African-American women, since higher incidence rates occur among African-American women prior to age 40, while the pattern is reversed after this age.

Specific information about breast cancer rates appears below. Incidence data are from the NCI's Surveillance, Epidemiology, and End Results (SEER) Program, a system of NCI-funded population-based cancer registries in nine U.S. locations.

Breast Cancer Incidence Rates (SEER): Under Age 50 - Between 1973 and 1991, breast cancer incidence increased 8.5 percent for white women under age 50; for African American women under age 50, incidence increased 26.1 percent. Age 50 and over - White women age 50 and over experienced an increased incidence rate of 31.8 percent; African American women in this age range experienced a 32.0 percent increase.

Breast Cancer Mortality Rates (U.S.): Under Age 50 - Between 1973 and 1991, white women under age 50 experienced a decline of 14.0 percent in breast cancer mortality rates; African American women experienced a 2.0 percent increase in mortality. Age 50 and over - Mortality from breast cancer increased by 4.0 percent in white women age 50 and over; African American women experienced a mortality increase of 26.3 percent.

Ohio Breast Cancer Statistics: (Incidence rates are not available as Ohio has not in the past collected state-wide population-based cancer incidence information.) Since 1953, Ohio has ranked among the top twelve states for breast cancer mortality. Of the 50 states plus the District of Columbia, Ohio currently ranks 11th for all women, 10th for white women, and 19th for African American women. For the period 1983-1987, the female breast cancer mortality rate for the nation was 27.16 per 100,000 women; by comparison, the Ohio rate was 29.13 per 100,000 for the same period. There were six counties in Ohio which had rates statistically significantly higher than the national rate per 100,000 women during that period: Clermont (37.8), Hamilton (32.5), Cuyahoga (31.5), Franklin (31.4), Lorain (31.4), and Montgomery (30.5).

Between 1988 and 1990, all U.S. counties with populations including at least 50,000 women were ranked based on their breast cancer mortality rates and compared for statistically significant differences from the overall U.S. rate (27.5 per 100,000 women). The six counties mentioned previously were all included in this comparison; only Cuyahoga (32.4) ranked significantly higher than the U.S. rate.

EARLY DETECTION

Early detection methods and state-of-the-art therapies clearly can save lives. Experts estimate that when a breast tumor is found in the earliest stages, the 5-year survival rate is 96 percent. Increased use of mammography has meant that tumors are being found at an earlier stage. The majority of women have localized and regional disease at initial diagnoses. Women are becoming increasingly aware of the need for early detection of breast cancer, but there is still a need for more information and reassurance that the choices they make are best for their individual profile. The NCI is addressing the issue of breast cancer awareness in a number of ways, including the production of videotapes on early detection, Spanish-language pamphlets and videotapes, co-sponsorship of regional breast cancer education summits with leaders of business and the local communities, and working through leadership initiatives to develop culturally appropriate and effective ways to communicate messages about early detection and prompt high quality treatment.

Mammography

In February 1993, NCI hosted an international workshop on breast cancer screening to review data from screening trials worldwide, including a Canadian study released in November 1992. The results of the February review showed that mammography and clinical breast exam definitely reduced deaths from breast cancer by about 30 percent in women ages 50 and older. The conference experts raised questions about the value of mammography in younger women. Essentially, meta-analysis has found no evidence of reduced mortality after seven years of follow-up among women ages 40-49 who were screened periodically with mammography, compared to the control group who did not receive mammography. Our knowledge may change in the future as women on these trials are followed and more information emerges over time. But we believe the facts as we know them for this important problem must be made available.

On December 3, 1993, NCI issued a statement of fact regarding mammography - facts as we know them today. The statement was based on the workshop and a nearly year-long effort that reviewed the workshop's results. This statement emphasizes that clinical trials prove that screening with mammography and clinical breast exam will reduce death from breast cancer for women ages 50-69. The trials show a reduction of about one-third in the death rate with regular screening at an interval of one to two years.

The trials to date, however, have not shown definitive results in women ages 40-49. The NCI had expected that the Canadian trial, for which results were published in November 1992, would provide clearer information on the value of mammography in this age group, but this was not the case. The results from this trial are controversial, although a recently published paper addresses many of the criticisms of that study. As a group, the results of clinical trials to date leave us with considerable uncertainty, and this uncertainty has polarized the medical and scientific communities. The NCI statement is based, in part, on a review of these trials by a panel of leading researchers. In the absence of definitive results or a consensus, we feel it is impossible for NCI to recommend unequivocally for or against screening for women in their forties. We believe it is critical that women and health professionals understand that there are both risks and benefits from mammography.

The decision to have mammography involves a balance between these risks and the potential benefit from finding the breast cancer and seeking proper treatment. It should be stressed that most experts recommend mammography in conjunction with clinical breast exam, as some clinical trials have been conducted with the two approaches performed together, and their effects cannot be completely separated. We are working with the American Cancer Society and other scholarly groups to see if there are certain women ages 40-49 for whom the positive predictive value of mammography would be high. We are continuing to strive for consensus. Furthermore, we at NCI believe it is important that all relevant Federal agencies work together in this area and we are encouraging those collaborations.

Imaging

We expect that in the future genetic discoveries will yield new molecular tests that might have high specificity for breast cancer. We are not simply waiting for this to occur. We are working to refine the tools we have, including mammography. In September 1991, NCI held a workshop entitled, "Breast Imaging: State-of-the-Art and Technologies of the Future."

Because of its promise, a working group was formed to focus on digital mammography. We are encouraging the development of new digital mammography techniques, which would also allow images to be transmitted for consultation or diagnosis by specialists. New imaging techniques are also being used to more accurately guide biopsies and surgery. Other methods are borrowing from technology developed in space or defense research for purposes such as target recognition. None of us is content with progress to date. We know first-hand the suffering caused by this disease.

RISK FACTORS

To some extent, breast cancer incidence appears to be linked to the conditions of life for modern women, such as earlier menstruation due to better nutrition, forgoing or postponing childbearing to pursue education or careers, or late menopause. Use of oral contraceptives and hormone replacement therapy may also contribute to the risk of breast cancer. A national tendency to eat a diet high in fat and calories and low in fruits and vegetables might play a role in the incidence of breast cancer. Furthermore, as people age and life expectancy lengthens in our society we see higher cancer rates.

Few diseases have had more intensive epidemiologic study than breast cancer, but unfortunately there remain a number of gaps in our knowledge about the causes of the disease. Estimates of the proportion of disease that can be attributed to known risk factors range from 30 percent to 70 percent, depending on the study population. These estimates take into account only the well established breast cancer risk factors, including early age at menarche, late age at first childbirth or nulliparity, a history of certain types of benign breast disease, late age at menopause, and a family history of breast cancer in a first degree relative.

There is extensive research interest in a number of possible risk factors, including alcohol, certain medications (such as antihypertensives and thyroid medications), hair dye, electromagnetic radiation exposures, heterocyclic amines (HCAs, compounds formed in cooked meats), plant estrogens, pesticides, and occupational exposures. The NCI is currently supporting research on these potential risk factors through their extramural and intramural programs. While a number of these factors are implicated as possible causes of breast cancer, research results have been inconsistent across studies, complicating their interpretation.

The NCI conducts a comprehensive program of laboratory and epidemiologic investigations on potential occupational and environmental hazards. The goal of these studies is to identify occupational and other environmental factors involved in the development of cancer so that preventive measures can be undertaken. The NCI's investigation into environmental hazards expanded in the 1960s, and was further strengthened in the 1970's and 1980's with the creation of several laboratories and branches within NCI dedicated to environmental epidemiology and carcinogenesis research. The NCI pioneered efforts in the field of toxicology testing early in the 1970s; however, NCI no longer performs routine carcinogenicity testing of chemicals in mice and rats. In 1981, the responsibility for managing the Carcinogenesis Bioassay Program and the necessary resources were transferred from NCI to the National Toxicology Program (NTP) of NIEHS. NCI is a member of the NTP executive committee and nominates the great majority of chemicals for high priority testing. Such nominations are based on environmental exposures, occupational exposures, production data, structural relationships to known carcinogens, and *in vitro* mutagenicity tests.

Recent attention has focused on the possible role of non-occupational exposure to pesticides in the development of breast cancer. One study in the mid-1970's raised concern about elevated levels of dichlorodiphenytrichloroethane (DDT) or its metabolite DDE, in tissue from breast cancer patients. However, two subsequent studies, published in 1984 (Unger, et al.) and 1990 (Mussalo-Rauhamaa et al.), found no such elevation. Then in 1992, Dr. Frank Falck and colleagues reported an association between levels of DDT, its metabolites, and polychlorinated biphenyls (PCBs) and risk of breast cancer. Earlier this year, Dr. Mary Wolff and colleagues published a similar finding in the *Journal of the National Cancer Institute*. In April 1994, Dr. Nancy Krieger published a study that did not support the hypothesis that DDT exposure is associated with increased risk of breast cancer. Further studies are needed to clarify this scientific question. The NCI funded the Krieger study, while NCI and NIEHS co-funded the original Wolff study. Collaborations also are underway with NIEHS on epidemiologic studies of breast cancer risks associated with polybrominated biphenyls (PBBs) and DDT. These studies have been initiated to determine whether the levels of organochlorine compounds in sera and tissue of breast cancer cases differ from those in controls.

Although both DDT and PCBs are no longer used in the United States (the EPA banned all uses of DDT in the United States in 1972 and prohibited the manufacture and use of PCBs after 1977), these compounds remain in the environment or, in the case of PCBs, in some of the older electrical transformer equipment still in use. Residues may make their way through the food chain to humans, primarily through meat and dairy products. In rodents, DDT and its metabolites have been associated with an increased incidence of liver and lung tumors. In three studies, the incidence of lymphoma was increased, while in two other studies the incidence of lymphoma was decreased. No studies have reported an excess of breast tumors in rodents exposed to DDT or its metabolites. In addition, in nonhuman primates DDT at maximal tolerated doses has not induced any cases of breast cancer and its carcinogenic potential is at best equivocal. PCBs are also associated with liver tumors, lymphoma and leukemia in rodents, but not breast tumors.

The NCI has several ongoing projects and has identified resources for other projects in which these provocative findings can be evaluated further. We are particularly interested in efforts that might allow us to disentangle the direct effects of the organochlorine residues from the possible effects of a high fat diet. This requires finding populations whose primary route of organochlorine exposure was other than through meat and dairy products. One such population is from Triana, Alabama, where a DDT production plant discharged large quantities of the pesticide into the Tennessee River for several decades before it was discovered. The nearby population consumed fish from the river and accumulated body burdens of the pesticide that were orders of magnitude above the general population. The heavy exposure through fish consumption and the availability of previously collected blood, adipose tissue, and risk factor information make this population a valuable study resource. The population is predominantly African-American, a racial group that has not been evaluated separately or included in the previously published studies. We are working with the Triana Area Medical Fund, Inc., the University of Alabama College of Nursing, and other health care professionals in the area to determine if it is possible to obtain the needed information for a study.

We are also pursuing a study of breast cancer in Alaskan Native women, whose diet includes a high intake of fish and marine mammals that typically have high concentrations of organochlorines. In collaboration with the Alaskan Area Native Health Service and the Centers for Disease Control and Prevention (CDC), we are establishing a pilot project using NCI funds to evaluate levels of organochlorines in stored sera and to validate medical record information on breast cancer risk factors.

Another project in which we will evaluate the role of DDT and other pesticides as possible breast cancer risk factors is the Agricultural Health Study, a large prospective study of pesticide applicators and farm families. This study, a collaborative effort of NCI, NIEHS, and EPA, will evaluate cancer risks in over 70,000 men and 40,000 women from Iowa and North Carolina. The project includes Caucasians and minority groups, extensive exposure information, and collection of biological samples from cancer cases and controls. We expect approximately 160 breast cancer cases will occur in the first five years of the study and 575 cases after 10 years. We are also currently competing contracts to support investigations of the feasibility of epidemiological research on migrant and seasonal farmworkers. The results will help us launch full-scale epidemiologic studies of pesticides in this often heavily-exposed minority and underserved population.

Breast cancer cases and controls within a cohort of Michigan families whose farms were heavily contaminated with PBBs, compounds closely related to PCBs, are also under study. Since 1976, NCI, CDC, FDA, NIEHS, and the Michigan Department of Public Health have collaborated in a project to monitor the health of this cohort. However, over an observation period of 17 years since exposures, results so far indicate that in this population there is no excess cancer incidence of any type, including breast cancer. We are currently evaluating the levels of PBBs and pesticide residues in blood collected from cases prior to the diagnosis of disease and from controls. Adipose tissue for the breast cancer cases and benign breast disease patients will also be collected from biopsy specimens available from hospital pathology departments.

Although DDT was banned in the United States, it is still used outside the United States. We have begun feasibility investigations with colleagues from India, which is among the countries with the highest current use and highest body burdens of DDT in the world. India provides an excellent opportunity to disentangle the effects of diet and organochlorines because of the diverse dietary patterns within the population. While DDT is still used by virtually the entire population for insect control, the potential intake through meat and dairy products varies greatly. Subgroups of the population are strict vegetarians (eating no meat or eggs), while others are ovalactovegetarians (who eat dairy and egg products), non-beef meat eaters, or beef-eaters. A full-scale study in India might be of value in addressing the relation between breast cancer risk, organochlorine body burdens and diet.

The NCI, in collaboration with NIEHS, has awarded six grants to evaluate environmental factors and breast cancer in high-risk areas of the northeastern United States. Over the next four years, the "Northeast/Mid-Atlantic Study" investigators will study potential risk factors, including organochlorines, electromagnetic fields, and environmental and genetic determinants, that may contribute to the high rate of mortality from breast cancer in this region. One of these studies includes a large cohort of Ohio nurses. These studies are being conducted with regional populations, and NCI recently asked the Cancer Information Service (CIS) for these states to emphasize and expand their efforts in outreach and information collection. This effort will ensure that all residents in the region have access to the same information about low-cost screening services; advocacy and support group contacts; regional NCI-funded cancer center activities; cancer registries; counseling services; NIEHS-funded Environmental Health Sciences Centers; information about NIEHS-supported Superfund hazardous waste activities; and NCI research concerning breast cancer.

In November 1993, NCI and NIEHS launched the Long Island Breast Cancer Study Project (LIBCSP), a Congressionally-mandated study of potential risk factors contributing to the high incidence of breast cancer in Long Island and two other counties in the Northeast. In order to quantify human exposure to several of the potential risk factors being studied, new technologies will need to be developed. We are working closely with other Federal and state agencies, utilities, and the scientific community, to explore all possible avenues of research collaboration. We have also been working very closely with the community to ensure that its concerns are incorporated in the development and execution of the LIBCSP. The entire project, including all components of the study in all phases, will require approximately five years to complete. The knowledge we gain from this study will be informative for all women, not only for those women on Long Island. Furthermore, this project is being carried out in close collaboration with other similar studies of potential breast cancer risk factors, including the Northeast/Mid-Atlantic study.

The NCI is also working with NIEHS, the NIH Office of Research on Women's Health (ORWH), and the National Institute of Child Health and Human Development to study the long-term and multigenerational effects from diethylstilbestrol (DES), a synthetic nonsteroidal estrogen, which was given to pregnant women to prevent miscarriages and preterm births between 1948 and 1971. The NCI maintains a commitment to the long-term followup of DES-exposed mothers and their *in utero*-exposed male and female children with respect to risk and development of breast, ovarian, and prostate cancer, as well as clear cell adenocarcinoma of the vagina and cervix in exposed daughters. Additionally, NCI is establishing a national DES education program for health professionals and the public to disseminate information and provide recommendations for physicians, DES-exposed women and their families regarding risks of DES exposure and standards of treatment.

Engine exhausts, which reach a large segment of the population, include complex mixtures of combustion products, such as polycyclic aromatic hydrocarbons, which are known carcinogens. A recent NCI study, conducted with the Institute of Carcinogenesis in Moscow, found that among Russian women, urban transport workers experience a significant excess of breast cancer. In studies designed to seek explanations for the high rates of breast cancer in the northeast United States, efforts will be made to elicit information on potential risks from exposure to motor exhausts and other pollutants.

The carcinogenic effects of ionizing and non-ionizing radiation are under intensive investigation. Ionizing radiation causes cancer at many sites including the breast, but risks at low levels from natural sources and medical uses are not well characterized. Of particular importance is a very large study of x-ray technologists, primarily women, who have low-level radiation exposure. The NCI has also initiated studies of Chernobyl workers who were involved in the clean-up process following the reactor accident. Electromagnetic fields (EMF) have been proposed as possible risk factors for certain cancers, especially leukemia and brain cancer. Although the experimental and epidemiologic data so far are inconclusive, NCI has launched several epidemiologic investigations, including a study of EMF and light and breast cancer, because of the public concerns and the universal occurrence of electromagnetic fields in our homes and at the work place.

We are seeking ways to enhance the research effort on occupational exposures among women and minorities. Over the past few decades, these populations have become an increasingly integral segment of the work force and have been encountering greater exposure to potentially toxic occupational agents. Nevertheless, only a limited number of studies have evaluated cancer risk from occupational exposures among women and minorities, and in particular the relationship between breast cancer and occupation. To correct these inadequacies, NCI, in collaboration with NIEHS, ORWH, and the National Institute for Occupational Safety and Health, sponsored an international conference on occupational cancer among women, including minority women, in November 1993. The meeting emphasized clarifying the methodologic problems and suggesting ways to overcome research and assessment obstacles, identifying data resources, defining research needs, and stimulating further research. Proceedings will be published this Fall in the *Journal of Occupational Medicine*.

In April 1994, the President's Cancer Panel held a meeting on "Avoidable Causes of Cancer," which was convened to review the definition of "avoidable" as applied to cancer, to examine predisposing factors for cancer, and to consider future research needs in the development and prevention of cancer. Although the definition of "avoidable" was not conclusively determined, the Panel heard presentations and moderated discussions on a spectrum of factors including tobacco and alcohol, diet and nutrition, hormones and medication, occupational and environmental exposures, radiation, and infectious agents. The Panel also invited speakers to discuss genetic susceptibility and environmental interactions, and the relationship of gender, ethnicity and living environment to all these factors. Future research should include finding ways to integrate basic science and epidemiology, collect data in ways meaningful to apply that information, and determine how to select and study populations to better target solutions.

BASIC RESEARCH

The NCI is committed to supporting the best, most appropriate, and comprehensive research on breast cancer. The coordinated breast cancer research program includes basic cancer research, prevention, treatment, rehabilitation, and community outreach. Important advances include greater involvement of women in making decisions about their clinical care, better chemotherapy, and broader use of lumpectomy and radiation instead of mastectomy where appropriate, often combined with hormone manipulation, new adjuvant therapies, and the new prevention interventions. Moreover, research targeted directly to breast cancer can bring some improvement in prevention, diagnosis and treatment, but an ultimate understanding at the molecular level is vital to achieving real breakthroughs and may also provide insights not only into breast cancer, but into other cancers, as well.

The NCI allocates about half its funds to the support of basic cancer research based on our overriding conviction that answers to breast cancer and other cancers lie in a more complete understanding of the cancer cell. Such research is focused on the cell biology of normal and malignant breast tissue growth. New approaches for evaluating precancerous breast cells are also being explored. Innovative clinical care, applied directly from the laboratory, is being accelerated by NCI's Specialized Programs of Research Excellence (SPORE), which foster interdisciplinary research on breast, prostate, gastrointestinal, and lung cancers. Currently we are funding nine breast cancer SPOREs.

Breast cancer is a very complex disease. Studies at the molecular level are providing information about family patterns and about inherited and acquired gene abnormalities that may influence the development and invasiveness of breast cancer cells. The early onset of familial breast cancer has been linked to inherited abnormalities in the "Breast Cancer-1" (BRCA-1) gene located on chromosome 17. There are several genes clustered in the BRCA-1 region that may also influence the growth and invasiveness of breast cancer. Many of the genes in this chromosome 17 complex also may be important in the pathogenesis of ovarian cancer and prostate cancer. The NCI is collaborating with the National Center for Human Genome Research (NCHGR) to dissect and identify the genes involved in many common malignancies, including the BRCA-1 gene in breast and ovarian cancer. Once this gene is cloned and sequenced, it should be possible to fully characterize its function and to develop genetic probes to identify members of breast and ovarian cancer-prone families who carry the gene and are at high risk for developing such cancers. The identification of a breast cancer gene for eventual clinical application is one of NCI's highest priorities, and will open whole new areas of breast cancer research. To this end, NCI issued a Request for Applications, which will be cofunded by the NIH Director's reserve fund, to clone and sequence the

BRCA-1 gene. This important area of research is on a "fast track" and NCI hopes to make awards by the end of this fiscal year.

Other studies have identified crucial genes and gene products that either promote or inhibit the development of cancer. A new genetic concept referred to as genomic imprinting is providing revolutionary insights into human heredity, particularly focusing on gene expression, which is dependent upon the gene inherited from the mother or father. Various patterns of genomic imprinting have been linked to certain inherited rare cancers, and may contribute to identifying factors involved in the etiology of cancer. In the Li-Fraumeni syndrome, families inherit a predisposition for certain cancers, including breast cancer. In 1990, researchers found that one of the causes of the syndrome is an alteration of the p53 gene on chromosome 17. This gene is a tumor suppressor that controls normal cell growth; when something goes awry with this gene, cancer may develop. If this is the case, women with a mutation of p53 may benefit from early preventive measures.

The role of growth factors is also under study. It is clear that breast cancer cells and their surrounding tissues secrete a number of growth factors and that the production of some of these growth factors can be controlled to some degree by the presence of estrogen. However, some estrogen-independent breast cancer cells have been shown to produce the same growth-stimulatory factors, thereby bypassing the need for estrogen stimulation. The entire range of growth factors and their inhibitors are promising agents for the treatment of breast cancer. For instance, the retinoids, chemical cousins of vitamin A, inhibit the growth of breast cancer cells by decreasing the production of such growth factors.

Vaccines offer opportunities for preventing cancer development, cancer recurrence or a new primary cancer in patients already treated for one malignancy. They may also be used for treating patients with active cancer. A potential new cancer vaccine, carcinoembryonic antigen (CEA) against breast and certain gastrointestinal cancers, has just been tested in patients for the first time earlier this year.

With the discovery of the genetic components of breast cancer, scientists are also working to use these components to increase the precision and sensitivity of diagnosis and the accuracy of prognosis for breast cancer. Blood tests may be able to identify carriers of the genes mentioned above; however, once reliable tests are available, patients and families will have to be carefully counseled regarding the implications of a positive test. Indeed, we are particularly concerned about the ramifications a positive finding will have on a woman and her family.

CLINICAL TRIALS: PREVENTION AND TREATMENT

Clinical trials research, important in developing new approaches to cancer treatment and prevention, is being pursued aggressively. Breast cancer clinical trials have led to the availability of improved diagnostic tests, have proven the value of less extensive surgery, have refined techniques used in breast reconstruction, and have increased survival through demonstrating effective chemotherapies. The NCI supports a large national network of Community Clinical Oncology Programs (CCOPs), Cooperative Groups, and Cancer Centers that provide state-of-the-art care for patients and perform clinical trials designed to develop better therapies. In 1971, NCI supported three comprehensive cancer centers; today we support 27 such centers across the country, together with 30 other specialized centers that receive grant support. The comprehensive cancer centers have a mandate to bring advances in cancer prevention, detection, and treatment to their communities and to develop strong links with community physicians and support groups. The Clinical Cooperative Groups Program began in 1975 and initially conducted small studies with few patients. The Groups now conduct approximately 35 breast cancer treatment trials that enroll 5,000 new patients each year. The establishment of CCOPs in 1983 created a network of community cancer specialists, primary care physicians, and other health care professionals who conduct clinical research on treatment, cancer prevention and control, screening, chemoprevention, smoking cessation, patient management, continuing care, and rehabilitation. The program involves more than 300 hospitals and nearly 2,500 physicians.

Last year, NCI launched a major breast cancer prevention trial to study tamoxifen, a hormonal agent long used to treat breast cancer. The study, conducted through the CCOPs, will enroll 16,000 women ages 35 and older who have been determined by a complex matrix of factors to be at high risk for breast cancer. About 280 centers in the U.S. and Canada are participating in this study, and about two-thirds of all the women who receive the risk assessment are eligible. Recent information about tamoxifen's association with endometrial cancer deaths among women being treated for breast cancer led to a temporary suspension of accrual of new patients to this trial; however, following careful review and recommendations by several advisory panels, NCI has authorized the resumption of risk assessments for women who are interested in joining the trial. Updated information regarding the risks and benefits associated with tamoxifen is being included in the informed consent document and each woman already enrolled in the trial has been notified of the changes. Currently, there are nearly 11,000 women enrolled in the trial.

Clinical trials serve as one of the foundation stones of the National Cancer Program. They are the real-world test of which new therapies (or preventive measures) will benefit specific patients. The key components of all clinical trials include careful and scientifically appropriate protocol design, informed consent, data management, quality control, and publication of trial results based on thorough statistical analysis. When all of these components are in place and functioning smoothly, we can have confidence in the results of clinical trials. When one or more of these components breaks down, we must identify the problem as quickly as possible and take action to repair it. The disclosure of data irregularities in National Surgical Breast and Bowel Project (NSABP) trials and the lapses of oversight at NSABP headquarters in auditing and reporting trials, and in publishing reanalyses of the affected studies with clear disclosure to the reader, required immediate corrective action on the part of NSABP and NCI in order to ensure the validity of NSABP trials.

To do its job more effectively, NCI has established a new Branch to oversee the quality assurance aspects of its large-scale clinical trials. More explicit guidelines for auditing and for dealing with data irregularities in clinical trials have been set in place, and NCI has undertaken a re-evaluation of its quality assurance program and is moving to strengthen key components. As for the NSABP and its leadership, the group has submitted a corrective plan of action, including provisions for on-site oversight by NCI staff. The NCI has found this plan for resuming trials to be generally acceptable subject to some clarification or modification and continuing oversight. Moreover, all parties - including the University of Pittsburgh - are committed to allowing the peer review process to determine the future location and scientific direction of NSABP's clinical trials administration.

We are pleased to report some recent important treatment advances against breast cancer. Treatment clinical trials supported by NCI have clearly established the effectiveness of systemic adjuvant therapies given after surgery. Trials have shown that adjuvant chemotherapy and/or hormonal therapy can reduce the cancer relapse rate by one-third. Breast cancer is the focus of more than one-third of our High Priority Clinical Trials, which are aimed at optimizing adjuvant (and neoadjuvant) therapies for breast cancer, including ductal carcinoma in situ (DCIS). Trials using neoadjuvant therapy - that is, chemotherapy given prior to radiation therapy or surgery to reduce tumor mass and increase the potential for cure - have yielded encouraging results.

For patients with Stage IV breast cancer, clinical trials of high doses of non-cross-resistant chemotherapy followed by autologous bone marrow transplant (ABMT) to "rescue" the patient from protracted bone marrow suppression are meeting with some sustained clinical responses in 15-20 percent of patients, especially those who had initially responded to conventional treatment approaches.

The impressive activity of Taxol® (paclitaxel) against advanced breast cancer has now been confirmed in patients with Stage IV disease, even in women who have relapsed or whose disease has progressed after initial therapy. The FDA thus approved its use in April 1994 for metastatic breast cancer. NCI played an important role in developing this drug, which is derived from the bark of the Pacific Yew tree. Many Federal agencies cooperated to increase the supply of paclitaxel, and over the past few years enough of the agent has become available to allow promising initial trials in lymphomas, head and neck, bladder, esophageal, and lung cancers, as well.

The ability to prevent metastasis - the spread of tumor cells from their origin to distant locations through the body - constitutes a novel form of secondary prevention, and could even serve as a method of primary prevention if we could learn how to stop tumor progression and dissemination. One target of such research is the metastasis suppressor gene NM23. The design of drugs to enhance the expression of the gene is an important initiative for NCI. The tissue inhibitor TIMP-2 blocks tumor angiogenesis (the formation and proliferation of new blood vessels critical to the process of metastasis) and holds promise for preventing secondary invasion and local tissue destruction by metastatic tumor deposits. CAI, which inhibits angiogenesis, is under study in diverse advanced malignancies, including ovarian, colon, breast, lung and renal cells carcinomas and melanoma. The Phase I clinical trial has now accrued 35 patients; approximately half have experienced disease stabilization.

BARRIERS TO HEALTH CARE

It is accepted that poverty and the effects of poverty play a major role in the high cancer mortality rates for certain groups of women. Lack of medical insurance and lack of access to early detection, prompt diagnosis, and state-of-the-art treatment lessen the chance of survival. Low income people have a higher incidence of cancer for all sites combined; 5-year survival rates for low-income women with breast cancer are 9 percent lower than the rates for upper income women. Low-income African-American women are more likely to first seek medical attention when their breast cancer is advanced. Culturally sensitive approaches to education are needed as well as strategies for improving access to screening and treatment for these groups.

In this regard, the NCI supports research identifying barriers to health care. A broad spectrum of prevention, treatment, rehabilitation, and community outreach programs has been designed to identify culturally appropriate interventions and to promote the needed behavioral changes, such as compliance with guidelines for effectively fighting breast cancer. An example of a very successful NCI-supported community outreach program can be found with the Leadership Initiatives, which include the National Black Leadership Initiative, the National Hispanic Leadership Initiative, and the Appalachian Leadership Initiative. All possess similar objectives: 1) to develop community coalitions that promote NCI's cancer prevention and control goals; 2) to mobilize community lay and professional leaders; 3) to implement effective cancer control intervention programs and strategies; 4) to stimulate data collection and research efforts; and 5) to evaluate the initiative. Also, using a networking approach, NCI has been able to channel cancer prevention and control information to attract and train culturally sensitive researchers and to provide technical assistance for the unique cancer needs of minority and medically underserved populations.

In 1991, NCI, with Revlon, the National Broadcasting Company, and the National Association of Broadcasters, participated in the professional production and distribution of a half-hour television program on mammography and early breast cancer detection called "Once a Year...for a Lifetime." The NCI and the other organizations offer the video to churches, clinics, senior citizens, and other television channels for community outreach activities. To reach Hispanic women, a Spanish-language version of this video was produced and distributed in 1992. It was broadcast by Univision, a Spanish-language television network.

The NCI and the Susan G. Komen Foundation of Dallas, Texas, have co-sponsored Regional Breast Cancer Education Summits across the country to enlist leaders of business, and of the community, voluntary, and health organizations in the effort to reduce deaths from breast cancer. The summits are usually hosted by NCI-funded cancer centers and other medical centers and provide community leaders with the tools to sponsor breast cancer education and screening activities and programs in their communities.

CANCER SURVIVORS: QUALITY OF LIFE

Over one million Americans will be diagnosed with cancer in 1994. Most will receive cancer therapy and supportive care during their illness, and about half will be alive and disease-free in five years. Thus, NCI-sponsored rehabilitation research is directed toward maintaining.the highest possible level of function and quality of life for the cancer patient during treatment, as well as enabling the cancer survivor to return to normal activities as soon as possible following treatment. Research efforts also encompass practical aspects of health care delivery, with initiatives in reducing the burden on those family and other community members who provide informal care for the cancer patient.

Because cancer represents a multiplicity of diseases, it may affect various parts of the body and its functions. The effects of cancer and its treatment on multiple organ systems and its effects on the individual's life are critical issues in cancer rehabilitation. Research must address the unique characteristics of each tumor and its therapy, as well as problems relevant to the needs of large numbers of people with any cancer. The broad range of topics being addressed reflects the complex and comprehensive nature of cancer rehabilitation.

Results of NCI-supported clinical trials have had a major impact on reducing the continuing care needs of cancer patients and improving their quality of life. Limb-sparing surgery for bone and soft-tissue tumors, procedures to preserve speech and swallowing function in cancers of the head and neck, multimodality approaches to breast conservation in early stage breast cancer, and surgical techniques to maintain sexual function in management of localized prostate cancer are examples of treatment advances that improve the long-term well-being of cancer patients.

Control of symptoms associated with cancer treatment is an important aspect of care for all patients undergoing active therapy. Efficacious management of treatment-related toxicities allows many patients to complete therapy and thus enhances delivery of state-of-the-art cancer care, as well as providing supportive care for patients receiving less aggressive treatment. Clinical research in the CCOP setting includes symptom control as a major focus. Studies include testing methods for prevention and treatment of chemotherapy-related mucositis, management of dermatitis associated with radiotherapy, effective antiemetic therapy, control of menopausal symptoms in women treated with chemotherapy or hormonal therapy for breast cancer, relief of cancer cachexia, and pain control. In addition, adding quality-of-life endpoints to cancer clinical trials is enhancing research efforts to optimize therapy yet minimize treatment-related symptoms. The CCOP network is currently conducting research to compare quality-of-life endpoints of different treatment options in clinical trials for breast, testicular, and prostate cancer.

Recently, NCI funded grants aimed at understanding and improving the lives of cancer survivors, including groups of cancer patients such as older women with breast cancer and rural cancer patients, from the point of diagnosis through treatment, paying special attention to psychosocial aspects of the disease.

OUTREACH

The NCI has an important mandate to inform the scientific community and the public regarding advances in our knowledge about cancer. The NCI has a long and very proud history of direct information dissemination to patients and health care providers. The NCI's Cancer Information Service (CIS) is available to physicians and the public through a toll-free telephone number (1-800-4-CANCER) which responded to about 600,000 calls last year. The CIS, which is a regionally-based service tailored to the communities it serves, also provides information to all Americans about clinical trials and state-of-the-art treatment through the computerized Physician Data Query (PDQ) system. Health care providers, patients and their families, and the public can obtain state-of-the-art treatment information from PDQ by calling CIS directly, through a personal computer, or via facsimile machine or Internet.

The NCI develops and distributes publications and conducts national educational campaigns about reducing cancer risk. This is done through the media and public meetings such as the field hearing today, and scientific meetings where immediate exchange of new information can be made to the medical, scientific, and lay communities. The NCI cooperates with other State and Federal government agencies who have regulatory responsibilities. We share findings with EPA, the Occupational Safety and Health Administration, FDA, and the Consumer Product Safety Commission through formal meetings and staff-to-staff discussions regarding our work. Recently we have held such discussions with EPA regarding pesticides and with FDA regarding hair dyes. We also work in coordination with various HHS committees, and with NIEHS, to ensure collaborative and complementary, not duplicative, research efforts into health effects of environmental and occupational carcinogens.

The NCI uses several other approaches to inform and advise the public on actions regarding breast cancer. For many studies and topics we develop fact sheets and press releases to apprise the media and the public of important findings. Statements have been developed for pesticides, hormone replacement therapy, oral contraceptives, and environmental exposures and breast cancer risk, to name just a few. Updates on NCI's research portfolio regarding cancer prevention and environmental carcinogenesis are available to the press and the public. The NCI holds press conferences to announce the commencement, or the results, of special initiatives. Pamphlets describing *What You Need to Know About....* various cancers are available, and include all known risk factors and preventive actions regarding the specific cancer.

As a further extension of this outreach, NCI staff regularly make presentations to various groups interested in specific topics and discuss the results and implications of NCI research at many other public forums on breast cancer. In these settings, practical aspects of our findings are noted.

Communicating information that asks people to review, consider, and possibly change basic lifestyle patterns takes thought, multiple message reinforcements and time. For example, the private sector, in particular the food industry, has been a willing and effective partner with government health agencies in the implementation of the "5 A Day" program and the development of a strategic plan to improve the American diet. Continued collaboration between health agencies and the private sector is essential if we are to reduce the burden of cancer in America.

CONCLUSION

We at NCI reaffirm our commitment to reduce death and suffering from cancer and this commitment is made with a full awareness of its awesome challenge. We have no illusions that this is an easy task. The Institute has a broad portfolio on breast cancer research, and is looking at the genetic basis for the disease, the role of growth factors and tumor promoters and inhibitors, environmental/occupational and lifestyle risk factors, chemopreventive agents such as tamoxifen and potentially new retinoids (4-HPR), new treatment advances such as Taxol®, potential new vaccines such as recombinant vaccinia/CEA, and the translation of laboratory discoveries directly to patient therapies through our SPORE programs for breast cancer.

With our three foundation stones - basic research, clinical trials in early detection, prevention, and treatment, and cancer centers - we believe we have made progress and will continue to make progress in the continuing battle against cancer. Further in-depth studies on the epidemiology of this disease will make valuable contributions to our understanding of the causes of breast cancer and to its prevention. I thank you for the opportunity to testify today, and would be pleased to answer any questions.

Mr. BROWN. Dr. de Freitas.

STATEMENT OF GABRIEL F. de FREITAS

Mr. DE FREITAS. Congressman Brown, my name is Gabriel de Freitas. I am a surgical oncologist, which is a fancy way of saying I do cancer surgery. I was trained at the Memorial Sloan-Kettering Cancer Center in New York City. After practicing cancer surgery in Phoenix, Ariz. for over 20 years, I was recruited to come to St. Joseph Hospital in Lorain to participate in and help in the development of the cancer program. I am also liaison officer with the Commission on Cancer of the American College of Surgeons. It is fortunate, and really very helpful, that this hearing should take place here, and at this time, because over the past year, we have been developing a comprehensive breast care center at our hospital, and this hearing will provide even further impetus to our efforts in completing that project.

Breast cancer is a disease much feared by women because it affects that part of the body in our society which represents the very essence of being a woman. It is the number one cause of death from cancer in women age 15 to 54. The incidence of breast cancer rose 1 percent per year in the 40 years between 1940 and 1980 but climbed to 4 percent per year in the 7 years between 1980 and 1987. This sharp increase probably reflects the increased number of cases that were detected by mammography. But we cannot exclude the possibility of an absolute increase in the number of women who are developing new breast cancers. Although the death rate, as has been mentioned, from breast cancer has remained essentially unchanged for 50 years, preliminary data, however, suggest that a 3 to 6 percent drop occurred in 1991 compared to 1990. If this trend holds up, this will mean that treatment is finally impacting the disease, again, probably through the detection of smaller, more curable cancers by mammography.

The face of breast cancer has changed over the 25 years since I completed a surgical fellowship at Memorial Sloan-Kettering. At that time, we performed up to seven radical mastectomies a day and today, I almost never perform one. Less mutilating surgical operations such as lumpectomy, which saves the breast, and modified radical mastectomy, have replaced the old so-called radical, because earlier cancers are being discovered. At present, our most effective weapon against breast cancer remains early detection through screening mammography, because a small cancer can be discovered this way 2 years before even the most skillful examiner can feel it. Cure rates for these cancers are in the 90 plus percent cure range.

Eventually, screening mammography, if more widely used, could help to control breast cancer just as the Pap test did in cancer of the cervix. The American Cancer Society recommends screening mammography every 1 to 2 years in the age group 40 to 49 and over 50, annually. However, the potential benefit of mammography is not being realized. While more women were being screened in the 1980's, currently fewer than 50 percent of eligible women are being screened, and in my opinion, the figure is probably closer to 30 percent. Mammography continues to be discouraged by a refusal of insurance companies to pay for it, and Medicare will pay for only one screening every other year in women over 65, and from the statistics that were shown to you, this is the very highest risk group, the over 65 year group.

However, even mammography is under-utilized even by the standards of Medicare. Only ⅓ of women over 50 have ever had a mammogram. The National Cancer Institute, with apologies to Dr. Sondik, has added to the confusion by retreating from prior recommendations that called for periodic screening in women under 50. Yet 20 percent of new breast cancers occur in this very age group. And mammography alone, without physical examination, can pick up 35 percent of these. If one considers that 1.5 million new cancers will be diagnosed in the next 10 years, a conservative figure is 105,000 women will be denied early detection and may die of the disease unnecessarily. And I mention this again, I repeat, this is a conservative figure. Screening mammography is more about saving lives than saving a few dollars.

Mr. Chairman, those of us who treat breast cancer daily urge uniform guidelines along those of the American Cancer Society. The testimony you have heard this morning show why we at St. Joseph Hospital are concentrating our efforts on the total care of breast diseases by establishing an on-site comprehensive breast care center that will offer bilingual education, breast screening, diagnosis and treatment through a multi-disciplinary program. This team approach will avoid duplication and conserve financial resources through efficiency and yet not jeopardize patient welfare.

One of the unfortunate consequences of our present health care delivery system is that patients fall through the cracks. With an integrated system, patients can be carefully followed. Once a tissue diagnosis has been made, the case will be evaluated by physicians in various specialties on our staff and treatment options will be discussed and then presented to the patient before final treatment. Psycho-social support will be initiated as soon as the diagnosis of cancer has been made.

We are fortunate at St. Joseph Hospital in having the only radiotherapy facility in Lorain County. Because at the present time, radio-therapy is absolutely essential in the vast majority of cases after lumpectomy, the radiation oncologist must be involved in the decision-making process as soon as the diagnosis is made. If mastectomy is required, consultation with a plastic surgeon will be offered to address breast reconstruction. The comprehensive breast care center concept is flourishing across this country, and many more such dedicated centers should be developed.

As Glynis Laing mentioned, St. Joseph Hospital also is currently participating in work site prostate and breast cancer screenings. Our philosophy is go to the patient if the patient will not come to you. Mobile units have provided on-site mammography. Work site breast screening will be the exciting outreach program for any hospital in the 1990's. Thus, by utilizing all that we already have available to us, we can find those early cancers, treat them and offer the best chance of cure.

Until something better comes along, our present weapons in the war against breast cancer should be used efficiently and persistently. In a country with the best health care in the world, we must provide women with absolutely nothing less and women should tolerate nothing less.

Mr. Chairman, I appreciate the opportunity you have given me to address this hearing.

Mr. BROWN. Thank you, Dr. de Freitas.

[The prepared statement of Dr. de Freitas follows:]

Statement of Gabriel F. de Freitas, M.D.
at the field hearing of the House Committee on Energy and Commerce
Subcommitte on Health and the Enviornment
August 1, 1994
Lorain, OH

Breast cancer is a disease much feared by women because it affects that part of the body that, in our society, represents the very essence of being a woman. It is the most frequent cancer in women and the second leading cause of death from cancer. It is the number one cause of cancer deaths in women aged 15 to 54.

The American Cancer Society estimates that in the United States 182, 000 new cases will be diagnosed and 46,000 women will die of breast cancer in 1994. In Ohio 8800 new cases will be diagnosed and 2200 deaths will occur in 1994. These statistics explain why breast cancer is a major health issue that unarguably presents all of us with as enormous a challenge as any other disease does.

The incidence of breast cancer rose about 1% per year between 1940 and 1980 but climbed to 4% per year between 1980 and 1987. This sharp increase probably reflects the increased number of cases that were detected by mammography during those years. But one cannot entirely exclude the possibility of an absolute increase in the number of women developing breast cancer.

Although the death rate from breast cancer has remained essentially unchanged for 50 years, preliminary data suggest that a 3 to 6% drop occurred in 1991 compared to 1990. If this trend holds up, this will mean that treatment is impacting the disease, probably through the detection by mammography of smaller and consequently more curable cancers. In fact, National Cancer Institute SEER (Surveillance, Epidemiology and End Result Program) data show that the increase in incidence in the 1980's was due to localized cases and cancers under 2cm in size, which are more curable.

The face of breast cancer has changed in many ways over the 25 years since I completed a surgical fellowship at Memorial Sloan-Kettering Cancer Center. Then we performed up to seven radical mastectomies in one day. Now I almost never perform one. Less mutilating surgical operations, such as lumpectomy, which saves the breast, and modified radical mastectomy have replaced the so-called radical because more curable cancers are being discovered by screening mammography.

Since we do not know the cause of breast cancer we cannot prevent it, although the oral antiestrogen drug, tamoxifen, shows promise in this area. Tamoxifen can achieve a 40% reduction of cancer occurrence in the opposite breast in women who have already been treated for one breast cancer.

At present our most effective weapon against breast cancer remains early detection through screening mammography because a small cancer can be discovered on an x-ray two years before even the most skillful examiner can feel it. Cure rates for small cancers are in the 90% range. Eventually screening mammography, if it would be more widely used, could help to control breast cancer just as the PAP test did in cancer of the cervix.

The American Cancer Society Breast Cancer Detection Guidelines for asymptomatic women include, monthly breast self-examination, annual physical examination by a health care professional and mammography every 1 to 2 years in the age group 40 to 49. Annual mammography is recommended for women 50 years of age and over. However, the potential benefit of mammography may never be realized; while more women were being screened in the 1980's, currently fewer than 50% of eligible women are being screened, and the figure is probably closer to 30%. Mammography screening is discouraged by refusal of insurance companies to pay for it, and Medicare will only pay for one screening mammogram every other year in women 65 years or older.

Even the National Cancer Institute has added to the confusion by retreating from prior recommendations calling for annual mammograms in women under 50. While this is based on data from the Canadian Trial that questioned the survival advantage in screening this age group, other randomized trials in the United States, United Kingdom and Sweden have observed a mortality reduction in women aged 40 to 49. Moreover, 20% of new breast cancers occur in women in the 40 to 49 age group, and mammography alone will detect 35% of these cancers. If one considers that 1.5 million new cancers will be diagnosed in the next 10 years, 35% of these women, or 105,000 women will be denied early detection. If you were one of those women screening mammography would be very important. Screening mammography is more about saving lives than saving a few dollars. Those of us who treat breast cancer daily urge uniform guidelines and universal adoption of the of the American Cancer Society.

We at St. Joseph Hospital and Health Center are concentrating our effort on the total care of breast diseases by establishing an on-site Comprehensive Breast Health Center, that will offer education, brêast screening, diagnosis, and treatment. While all of these are currently provided by individual health professionals, establishing a breast center at the hospital will provide a multidisciplinary program which will include radiologists, primary care physicians, gynecologists, surgeons, pathologists, medical oncologists, plastic surgeons, radiation oncologists, oncology nurses, social workers and psychologists, who already are on our hospital staff. This team approach will avoid duplication and conserve financial resources through the efficient use of the shinking medical dollar without jeopardizing patient welfare. Patients can be self referred or physician referred.

One of the unfortunate consequences of our present health care delivery system is that patients "fall through the cracks". With an intergrated system patients can be followed and recalled as necessary. If a breast cancer is found, biopsy under local anesthesia on an outpatient basis will be performed. Those cancers that cannot be felt will be localized and biopsied by needle localization or by stereotactic biopsy. Once a tissue diagnosis of cancer has been made, and prior to any surgical treatment, the case will be evaluated by physicians in various specialities, treatment options will be discussed and then presented to the patient. Psychosocial support will be initiated as soon as the diagnosis of cancer has been made. Bilingual literature will be available to assist the patient in evaluating the recommended option and facilitate her decision. Multimodality treatment will be utilized, as it is today, i.e. radiotherapy if lumpectomy is done and chemotherapy or hormonal therapy if lymph nodes are involved or the tumor has poor prognostic biological behavior characteristics. We are fortunate at St. Joseph Hospital and Health Center in having the only radiotherapy facility in Lorain County. Because radiotherapy at the present time is essential in the majority of cases after lumpectomy is carried out, the radiation oncologist must be involved in the decision-making process as soon as the diagnosis has been made. If mastectomy is required, consultation with a plastic surgeon will be offered to address reconstruction, either delayed or immediate. The Comprehensive Breast Health Center concept is flourishing across the country and more such dedicated centers should be developed.

We at St. Joseph Hospital and Health Center are also currently participating in worksite prostate and breast cancer screenings. Our philosophy is: "go to the patient if the patient won't come to you". The work site may be the optimal place for cancer screening since workers will be comfortable in familiar surroundings and more likely to accept screening. Mobile mammogram x-ray units have provided onsite mammography at the work place. Patients will be referred to the Breast Center for further mammography if magnification views of the breast abnormality are required. Worksite screening can be the exciting outreach program for any hospital in the 1990's.

Thus by utilizing all that we already have available to us we will find the early cancers, treat them and offer the best chance for cure. Until something better comes along our present weapons in the war against breast cancer should be used efficiently and persistently. Here is our best chance to control breast cancer. In a country with the best health care in the world we must provide women with nothing less and women should accept nothing less.

Mr. Chairman, I appreciate the opportunity you have given me to address this hearing.

Mr. WAXMAN. Dr. Schulte, please.

STATEMENT OF PAUL SCHULTE

Mr. SCHULTE. Thank you, Mr. Chairman, ladies and gentlemen. I am Paul Schulte, I am a Senior Epidemiologist in the Industry-Wide Studies Branch of the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention. NIOSH, as we are called, is the Nation's agency responsible for dealing with health hazards of people at work.

I thank you for the opportunity to testify today about what is known about the role of occupational and environmental factors in breast cancer and its implications for addressing these concerns in northeastern Ohio. You have my full text of remarks. I will focus mostly on the kinds of research that we are doing to address one segment of the possible risk factors involved with breast cancer.

The main message that I have for you today though is that we know very little about the occupational and environmental causes of breast cancer. And in fact, researchers pretty much have focused on the hormonal factors, factors related to child-rearing and have not really looked at environmental and occupational factors. Maybe it is time to look deeper in that area; maybe we have missed some clues; maybe there are some leads there that need to be followed.

As Dr. Sondik and others have pointed out, the risk factors that we do know, the ones that pertain particularly to hormonal activity, and particularly estrogen, do not appear to explain all the breast cancers that currently exist. And so consequently, other hypotheses are being investigated.

You have heard reference to some of the research that has come out in the last few years that have looked at a group of chemicals, organic chlorine-containing chemicals, or organo-chlorines. There have been about six major studies that have been looked at in this regard. Clearly one of the most famous is the study by Wolff and colleagues from Mount Sinai that looked at women in New York City. It was the big study that identified the DDT metabolite, DDE, as a possible risk factor for breast cancer.

When comparing women with breast cancer to women without breast cancer in this and a number of other studies, investigators noted a preponderance of higher levels of some of these organo-chlorine compounds, such as DDE, in the women with breast cancer compared to the women without breast cancer.

A larger study was recently released conducted in California using the Kaiser Health Plan population. This study did not confirm that earlier finding. And in fact, there was no increased level—or no difference really in the level for most women in the DDT metabolite, DDE, when you compared people with disease and without disease.

But these studies have had a number of limitations. For example, most of them looked at the organo-chlorine level at the time or near the time of diagnosis. Few—only one really—looked prior to the time of diagnosis, prior really to the time of the development of cancer. And we think this is an important thing to do.

Second, they involved only looking at a few organo-chlorines. It is not likely that any one organo-chlorine is going to be the cause, because we know organo-chlorine works by manipulating hormones, particularly estrogen. So it might be better to look at a variety of organo-chlorine compounds.

And third, most of the studies that have been conducted have been generally pretty small. And so they do not have the statistical capability of necessarily detecting an effect, in some cases when it might be there.

At NIOSH, we are doing three investigations to address some of these questions involving organo-chlorines. The first study we are doing is that we are utilizing banked blood. It was collected in Norway, but its utility is that it was collected up to as much as 20 years ago, and so we can look at women in this blood bank who developed breast cancer, and compare them to women in this bank who did not develop breast cancer. And we are also picking them from high potentially exposed occupations. And we will be able to see whether or not the levels of organo-chlorines are higher in people with breast cancer and without breast cancer. And instead of just looking at a handful of organo-chlorines, we are going to look at about 50 different ones because it might be that it is the total burden of these chemicals rather than any particular one that is important.

A second study that we are doing to address the organo-chlorine question is that we have assembled the largest cohort, the largest group of workers, maybe in the world, at least that has been assembled, that has had exposure to PCB's, polychlorinated biphenyls. These were women that worked in New York and in Massachusetts in the manufacturer of capacitors. We had assembled them to do a mortality study, but we feel that to get to the question of the risk of breast cancer from PCB exposure, it is best to do an incidence study, to look at the number of new cases that develop. So what we will do is follow this cohort, identify all the cases and then interview them so that we can assess their risk factor history. Thus, we will not only have occupational information, but we will also have important personal history, reproductive history and so forth. By doing that, we should be able to give a good bit of information about the role of polychlorinated biphenyls. We will have assessed in detail their occupational exposure history.

Organo-chlorines are chemicals that may act—by affecting hormones and modulating hormones, and they are called promoters in cancer biology. They do not necessarily start cancer, but they move the growth of cells along, and they may influence the transformation of cells.

What about chemicals that might affect DNA and start cancer? We call them initiators. Well, we are doing another study of a substance known as ethylene oxide. Ethylene oxide is used in this hospital probably and in most hospitals to sterilize instruments. It is also used to sterilize medical equipment and spices and various kinds of products. We have also assembled the largest group of women who have ever been exposed to ethylene oxide and we have done a detailed reconstruction of their exposure history. The reason we picked ethylene oxide is because it is an alkylating agent, it affects DNA, it has been shown to cause mammary tumors in laboratory animals, and it is a widely used chemical. So we have this large group of over 12,000 women and we have in-depth measurements of exposure on these women and a reconstruction of their exposure history using what we call a job exposure matrix, which is a mixture of taking measurements plus records of historical processes and really trying to recreate what a person has been exposed to. And we will do an incidence study in this group just like the incidence study I described for PCB's where we will get all the new cases plus get information about their medical and personal history. And by putting those together, I think we will be able to then contribute some information about the role of a substance that actually could start cancer as opposed to a substance that promotes it.

Finally, Mr. Congressman, I would like to make a couple of recommendations with regard to what kind of research is useful in this area. And I think the main recommendation is that we need more occupational studies of women. That might sound simple, but in fact women have been excluded from many of the epidemiologic studies that have been conducted, historically by many parties, be it government, academia and so forth. So we need to assemble and find more cohorts of women, and it may involve amassing them from a number of different workplaces, which has its own methodologic problems, but we need to build the right size groups, assemble the right size groups so that we can answer some of these questions about the occupational hazards to women with regard to breast cancer.

The second recommendation that I have is that when we do these kinds of studies and in other studies that are planned, that we take more measurements of the exposure that women will have to some of the candidate suspect agents, such as organo-chlorines, that is that we do more measuring of their air exposure in the workplace, or their dietary exposure, and then we take more biologic measurements, such as the suggestion of measuring organo-chlorines or taking breast milk and looking for substances there. So that we take more biologic measurements. These are controversial hypotheses about organo-chlorine and a lot of speculation can run fairly fast that they are causal in breast cancer. We do not really know that. We have a lot of circumstantial evidence. We need the details and the details come from the measurements that show them in tissue, measurements that show them in biologic specimens and when we can find specimen banks, all the better. So that is the second recommendation.

And the third recommendation is that we do more studies that include the variety of risk factors that women are exposed to in the right temporal patterns, so that we look at a woman's whole reproductive history, we look at longer periods of time and we look at exposures that could have occurred well before the actual diagnosis of the cancer, so that we can get a better handle on what could be causal and we can then have better ideas about what could be preventive.

I would be glad to address any other questions that you might have. Thank you.

[Testimony resumes on p. 124.]

[The prepared statement of Mr. Schulte follows:]

STATEMENT OF

PAUL SCHULTE, PH.D.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
CENTERS FOR DISEASE CONTROL AND PREVENTION

Mr. Chairman and members of the Subcommittee, I am Paul Schulte, a senior epidemiologist in the Industrywide Studies Branch of the National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC). Thank you for this opportunity to testify on what is known about the role of occupational and environmental factors in breast cancer and its implications for addressing concerns about breast cancer incidence in Northeast Ohio.

Relatively little is known about occupational or environmental risk factors for breast cancer. The established risk factors for breast cancer generally relate to a woman's age and family history of breast cancer along with her reproductive and hormonal history. Many of the risk indicators may be influenced by occupational factors. In some jobs or careers, women may tend to delay or forego parenthood or have few children. Increased mother's age at the birth of the first child, and decreased childbearing are known risk factors for breast cancer, as are a family history of breast cancer, early age at menarche and late age at menopause. All of these factors may involve a hormonal component, particularly estrogen. A few studies have shown moderate elevation in the risk of breast cancer among women without a history of strenuous physical activity, which also may operate through an estrogen or estrogen-related pathway.

Some researchers have hypothesized that various environmental factors are associated with breast cancer. Chief among these is dietary fat content, which has been a major research focus for more than a decade. Although the possibility of preventing breast cancer through dietary changes had initially been highly promising, recent studies have cast more doubts on this approach. A recent editorial in the Journal of Epidemiology concludes: "Unfortunately the optimism that was originally based on ecologic studies and sustained by results in case-control studies has not been confirmed in most cohort studies...the lack of support for the dietary hypothesis leaves us with options of searching for methodologic flaws in studies of dietary fat and breast cancer, framing new hypotheses relating to other aspects of diet, and reconsidering nondietary risk factors."

Another controversial hypothesis is that chemicals in the workplace or the environment that act like estrogen may be risk factors for breast cancer. Organic chlorine compounds, such as DDT, PCBs, dioxins and various pesticides are one such group of "hormone modulators." Various studies have raised this possibility.

A study of breast cancer among women in New York City (conducted by Wolff and colleagues at Mt. Sinai) measured a DDT metabolite and PCB levels in blood drawn within six months of diagnosis. Measurements from women with breast cancer were compared to measurements from women without breast cancer, matching the "cases" with "controls" according to menopause status, age and date at donation of blood, and day of menstrual cycle at time of first blood drawing. The investigators observed a statistically significant excess of DDE, a metabolite of DDT, and an excess of PCBs, which was not statistically significant, in people who developed breast cancer. This raised but could not prove the possibility that DDT exposure increases the risk for breast cancer.

Another study of breast fat in cancer cases and controls (Mussalo-Rauhamaa et al., 1990) found a statistically significant elevation of another organochlorine, beta-hexachlorocyclohexane, in breast cancer adipose tissue.

In contrast, researchers (Krieger et al., 1994 at the Kaiser Foundation Research Institute) who compared women with and without breast cancer in the California Kaiser Health Plan, were unable to find statistically significant increases in serum organochlorine (DDT, DDE, PCBs) levels, although in general, women in the study with breast cancer had higher levels than the women without breast cancer.

One problem with most of these studies is that the blood levels were measured at or near the time of diagnosis, thus not providing much information on whether the organochlorines were themselves the cause in the development of breast cancer. For most cancers, it is assumed that exposures 10 to 30 years prior to the diagnosis are more relevant than recent exposures, but because estrogens may cause cancer by a different mechanism--acting as promoters--a shorter time may be more relevant.

NIOSH researchers are studying the relationship between breast cancer and organochlorine exposure in two ways. First, we are utilizing banked blood to determine whether serum levels of these chemicals taken 5 to 20 years before diagnosis are higher in women who develop breast cancer than women of the same age who did not develop cancer. This study will use the Janus Blood Bank in Norway which has been storing blood specimens since the early 1970s. We will select women from the bank who are in occupations with high exposure to organochlorines and follow them using the Norwegian Cancer Registry and Census to determine if high levels of serum organochlorines are associated with breast cancer. More than 30 different organochlorine compounds such as PCBs, DDT, mirex dioxins, hexachlorobenzene and dieldrin will be analyzed in the serum of cases and controls.

The second approach NIOSH is using is to conduct an incidence study--that is, measuring the numbers of new cases of breast cancer diagnosed--in a cohort of 13,000 women from New York and Massachusetts exposed to PCBs, a group of chemicals known for their solubility in fatty tissue and estrogenic activities. This is the largest and best defined female cohort in the United States with PCB exposure.

Another CDC study that looks at the relationship between serum organochlorine levels and breast cancer is being conducted by CDC's National Center for Environmental Health. Banked blood samples from Native Alaskan women with dietary exposure to DDE are being analyzed to determine if levels are higher among women who subsequently (at least five years later) developed breast cancer, compared with women who did not develop breast cancer.

Evaluating incidence, as opposed to mortality, is advantageous for studying breast cancer among occupational cohorts for two reasons. First, mortality may not be the best outcome to measure for breast cancer, because in the U.S. the five year survival rate for white women is over 75 percent and for black women is over 60 percent. Second, without information on non-occupational risk factors, particularly reproductive history, it is difficult to determine whether an observed excess in breast cancer mortality is due to chemical exposures or to other factors such as delayed childbearing.

These difficulties can be overcome by studying breast cancer diagnosis or incidence rather than mortality and by asking women about their non-occupational risk factors. NIOSH researchers will contact each of the surviving members of the cohort to administer a questionnaire on cancer status, and reproductive, occupational and other risk factor history. This information will be combined with plant records and exposure information.

Other occupational risk factors for breast cancer may also exist but few studies of breast cancer etiology have addressed occupational and environmental chemical exposure and many cancer studies of industrial cohorts have excluded women.

Potential breast carcinogens are not limited to estrogenic chemicals. Agents that act directly on DNA, such as chemical alkylating agents and radiation, have also been shown to be carcinogenic in mammary tissue in animal studies and in humans. Although chemicals that induce breast cancer in humans have not been defined, it is a reasonable concern that chemicals that produce mammary tumors in rodents may act similarly in humans.

One such chemical is the alkylating agent ethylene oxide, used in hospital sterilizers. In a well-designed laboratory study, ethylene oxide caused significant excess cancer of the mammary glands in mice. Only 1 of 49 unexposed mice developed a mammary gland tumor, versus 8 of 48 mice exposed to 50 parts per million (ppm) and 6 of 49 mice exposed to 100 ppm.

To determine if women exposed to ethylene oxide are at increased risk of breast cancer, NIOSH will conduct an incidence study of 9,929 women involved in the commercial sterilizer industry. This will be the largest study of women exposed to ethylene oxide. The average year of first exposure was 1970, and the average length of exposure was 5 years. Based upon known incidence rates and the age distribution of the cohort, we estimate that 220 cases of breast cancer would be expected in this cohort through 1991.

This same cohort was developed for a previous NIOSH mortality study. This group has an important advantage in that an estimate of ethylene oxide exposure was developed for each worker, for each job held throughout her employment. Over 2,300 personal samples were obtained for the 1979-1985 period at 12 different plants, and these, as well as knowledge of historical processes, were used to estimate exposures. The resulting information forms what is known as a "job-exposure" matrix. This matrix has been cited as one of the better estimates of historical exposures in occupational epidemiology, and it permits quantitative dose-response analyses which can rarely be done in historical epidemiologic studies. Using the job-exposure matrix, we will be able to determine whether the risk of breast cancer increases with increasing dose. Non-occupational risk factors such as reproductive history will be assessed by questionnaire.

Other occupational, environmental, and behavioral risk factors that have been investigated include ionizing radiation, electromagnetic fields, and physical activity. Ionizing radiation is an established cause of breast cancer in both animal and humans, but the human data are mostly from the atomic bomb cohorts in Japan. Relatively few data are available with which to assess the long-term effects of very low levels of radiation from occupational or medical diagnostic procedures. An increase in breast cancer risk has been reported for radium dial painters and for medical diagnostic radiology workers. No studies are available with which to directly evaluate the potential risk associated with radiation exposure from mammography.

At least six studies of women in occupations with exposure to electric and magnetic fields have shown no increased risk among those exposed. However, a recent study by Loomis and colleagues at the University of North Carolina reported that women in these occupations were more likely to die of breast cancer.

To better understand the role of occupation in breast cancer, NIOSH researchers used 2.9 million occupationally-coded death certificates from 23 states between 1979 an 1987 to calculate mortality ratios for breast cancer according to occupation. We found a number of significant associations between occupation and frequency of breast cancer. For example, white female professional, managerial and clerical workers all had high proportions of breast cancer deaths. For white women, the proportionate mortality ratios for clergywomen, librarians, and teachers were statistically significant and were more than 50 percent higher than expected breast cancer mortality rates for all white women. Black clergywomen and librarians had similarly elevated proportional mortality ratios. Black teachers had double the expected frequency of breast cancer mortality. For both black and white women, primary, secondary and post-secondary teachers all had increased rates of breast cancer mortality. Teachers accounted for more than five percent of all breast cancer deaths in the study.

No established workplace exposure explains this increased risk. It is most likely that occupational choices and accompanying life-styles reflect non-occupational risk factors for breast cancer relating to childbearing, diet, and contraceptive use. Census data provide indirect evidence that one of the well-established risk factors for breast cancer--increased maternal age at first birth-- is prominent in women with educational and occupational profiles like those identified as high-risk in our analyses.

Alternatively, these deaths may represent the existence of other yet unidentified risk factors. However, several surveys also indicate that better educated women are more likely to have regular mammograms. Using data from the 1990 National Health Interview Survey, NIOSH researchers found that women with blue collar and service jobs of any race, ethnicity or education category did not utilize breast cancer screening as much as recommended in the Department's Healthy People 2000.

In summary, the role of occupational and environmental factors in breast cancer is inadequately understood and continues to be studied. No specific risk factors (other than ionizing radiation) have been confirmed by research to date. NIOSH is working to improve the state of this field of research. Further progress will be needed before we can evaluate any associations between the incidence of breast cancer in Northeast Ohio and industrial and occupational profiles of the region.

To better answer questions about potential occupational or environmental factors in breast cancer, NIOSH recommends the following:

1. More occupational and environmental studies have to include women, who have often been excluded from many studies in the past.

2. More research has to include the measurement of exposures to hypothesized agents or chemicals such as electromagnetic fields or organochlorines. This research should include measurement of potential carcinogens in tissues and other biological specimens.

3. More studies are needed of women that include time periods long enough to account for the long latency between exposure

and disease that is generally associated with occupational and environmental carcinogens.

4. Other studies can be conducted over shorter time periods reflecting a role of estrogen-like chemicals as promoters. Such studies should assess the interactions of known and suspected risk factors. Since the role of environmental factors in breast cancer is likely to occur in conjunction with other potential causes, these factors need to be considered together.

While we continue our research on the etiology of breast cancer and search for opportunities to prevent the occurrence of this disease, we must also promote the use of early detection strategies that have been proven to save lives. The results of clinical trials over the past 30 years have shown us that more than 30 percent of the deaths from breast cancer in women over the age of 50 are preventable through the routine application of screening mammography, and timely and appropriate follow up and treatment.

As the Nation's Prevention Agency, CDC has been charged with ensuring that the public health system responds to this need. Since 1990 CDC has guided the implementation of the Breast and Cervical Cancer Mortality Prevention Act, Public Law 101-354. This legislation, which identified breast and cervical cancers as a major public health challenge, laid the foundation for a nationwide effort designed to increase the utilization of screening mammography and the Pap test.

The CDC-funded National Breast and Cervical Cancer Early Detection Program provides resources to State health agencies and national voluntary and professional organizations to increase awareness of the value of detecting breast cancer at early stages. The goal of the program is to increase screening utilization among all women, where it is deemed appropriate, with a special emphasis on women who are of low-income, racial and ethnic minorities, and the uninsured and underinsured. With appropriations of $78.0 million in Fiscal Year 1994, 45 states now participate in this exciting public health program at some level, including Ohio, which has a grant of $2.6 million to implement a comprehensive program. These innovative programs include outreach efforts, public and professional education activities, quality assurance efforts, appropriate surveillance and evaluation activities, and payment for screening services for eligible women. This national breast and cervical cancer control program provides a cancer control infrastructure that will complement clinical preventive services.

That concludes my remarks. I would be pleased to respond to any questions that you may have.

Mr. BROWN. Thank you, Dr. Schulte.

Dr. Sondik, a number of women have raised questions to me about the ongoing research at NCI. Given the age of women who continue to be diagnosed with breast cancer and the role that estrogen and hormones appear to play in development of the disease, I am interested to know a little bit more about what you are doing with that link. Should women be concerned about their choice of contraceptives or older women be concerned about their use of estrogen replacement?

Mr. SONDIK. Well there is ongoing research on both of those. Let me talk about the second one first. I think the second one is of considerable concern. The long-term use of estrogen replacement therapy has not been proven to be completely safe and it is one of the foci of the Women's Health Initiative that is underway. I think one needs to be circumspect here in the use of this regimen, and I think committing early on during menopause to a lifetime of this therapy should require a second or third opinion. I am not a physician, I do not want to make a unilateral medical recommendation—but what I can do is point out that the research community feels that the answer is not known and is still being pursued.

As far as the use of methods for birth control, this is something that is under study. The results at this point are not definitive. Dr. Obrams may have more information about that.

Ms. OBRAMS. The National Cancer Institute, some years ago, launched a large study of breast cancer in young women, young women under the age of 45, in a number of sites in the United States. And the results of that project, which focused especially on the use of oral contraceptives and oral contraceptive history, but other things as well, including occupation and environment, are just now under analysis and should be ready for distribution and dissemination shortly. We are certainly focusing very much on getting that information out as quickly as we can when the analyses are complete.

Mr. BROWN. Dr. Sondik, women are real frustrated with the misinformation that they get from physicians. I have heard a number of women say the myth they hear when they go to their doctor, things like you are too young, you could not have breast cancer, or if the lump hurts it cannot be cancerous, or the hereditary risk is only if it is on your mother's side of the family, if only your mother's side of the family has breast cancer, not your father's side of the family. What can NCI do about dealing with these kinds of myths and seeing doctors give more accurate information to their patients?

Mr. SONDIK. I think we can do a great deal, and I think we have to do it but not through a single channel. For example, developing a booklet that focuses on this information that we can make available to physicians is important. I think we need to do it in cooperation with the American Cancer Society, which has been very effective at providing this information. Certainly some information is available, but whether physicians are taking advantage of it to the extent that they should is perhaps another question. The comprehensive cancer centers and other cancer centers that we sponsor can have a major role in this. My understanding is that the one at Ohio State has been putting together a series of videotapes that are being made available to the public through one of the video stores nationwide. I think we need to do things that are innovative along those lines.

The point about misinformation really hits home with me, because I do think that we are in a position to address the medical community with the latest facts, and perhaps one of the things we should do is conduct a survey to give us information on exactly what the current knowledge is, and then be able to use that to buttress the information dissemination activities that we have. I think that always helps. Otherwise I think physicians and others look at this and say it does not apply to me because I certainly see the picture clearly.

Could I make one comment about mammography?

Mr. BROWN. Sure.

Mr. SONDIK. I think it is a very important topic, speaking of misinformation and confusion. I think that the NCI's position on this I would like to make very clear. What has happened is that information that we thought we had that mammography for women in their 40's would in fact reduce mortality is not borne out by the most recent trials. Now that does not mean that mammography will not reduce mortality for these women. It simply means that we do not have that information. We feel that the best thing that can happen for women when they turn 40 is to learn the facts about this, discuss it with their physicians who hopefully will also know the facts, and we will take every effort to make sure that they have those facts, and then make a reasoned decision. If a woman should decide that mammography is for her, that is fine, and she should be comfortable with that. If she decides that she wants to wait, for a variety of reasons, including the errors inherent in mammography and the likelihood at that age that she might develop breast cancer, that is a personal choice, and I do not think anyone at this point can dictate it.

There are several organizations that recommend mammography, including the American Cancer Society, American College of Radiology and others. There are several other organizations that do not, such as the U.S. Preventive Services Task Force. If experts all agreed, then I think the NCI could issue its own recommendation. But we do not have the clinical trials that prove it at this point and we do not have agreement in the expert community. And for that reason, we have said that we think it ought to be up to the individual. But we are most certainly not against women having mammography and I think that is a very important point, because I think our position has been portrayed as that.

Mr. BROWN. I beg to differ, women are dying while we are waiting to find out if it really should be 50 or if it should be 40. Women have come to me and have been on this panel that are 32 and 36 and occasionally 29 and 43 and 48 where doctors themselves are not—you say it is up to the individual, certainly it is, it is always up to the individual in consultation with her or his doctor on any disease. But when doctors are not giving the information or are simply not thinking of it or not advising it—there is a study in Sweden that said that mammography screening for women under 50 saved lives significantly. I think the worse part about the NCI's inability or unwillingness or whatever word you want to choose to come down on the side of let us do a little earlier detection is the sort of trickle down. If someone as reputable as you, Dr. Sondik, and some organization as reputable as NCI is saying we are not sure that it will do anything, that it will save lives if we do not do it before 50, then the insurance companies follow suit. And women who do not get enough information anyway from their physician may read in the paper that it is 50. I mean it just seems—I think Dr. de Freitas said that this is more about saving lives than saving a few dollars, and I think you can make the case that it saves dollars too if you do earlier detection because it is a lot cheaper to do a mammogram than it is to do later, more serious mastectomy instead of lumpectomy or more serious surgery later than earlier. And I would just implore you at NCI to (1) speed up and (2) make that decision that it should be baseline at 35 to 40 and every other year at 40 and every year at 50. It is just simply a situation where so many people are looking to you, women are looking to you, insurance companies are using you as an excuse and that simply should not continue.

Dr. de Freitas, you wanted to comment?

Mr. DE FREITAS. I have difficulty with the NCI recommending comprehensive breast care centers and then denying the very thing that is a non-invasive test that picks up by mammography alone 35 percent of malignancies. These cases can be saved, in situ ductal cancer can be saved. If there is one death involving in situ ductal cancer, that is unforgivable. That is the type you pick up at this age group with calcifications.

And then to cite the Canadian study which I think you are relying on, was very heavily over-weighted toward women who had lumps and the mammogram added nothing to saying they had breast cancer. And this is their major dependence, is that Canadian study. It has been absolutely disproven by the majority of studies elsewhere. To review this at a time when mammography is doing this in the country, I think the thing is that women's groups should just knock on your door starting tomorrow morning. Maybe you could give out your card and your phone number.

Mr. SONDIK. They are knocking on the door and they have been for quite some time.

Mr. DE FREITAS. Good.

Mr. SONDIK. The door is getting worn away.

Let us say that in fact we do more trials. A trial is beginning in England, and we are going to help support that, which is probably the best trial design that could be done to see if we can get an answer to this. And let us say that in fact it turns out that it is negative. Then where are we?

I do not know quite how to say this so that it does not sound negative. We are not telling women to have mammography or to not have mammography. The fact is that whether the Canadian trial is included or not—and it is controversial—we do not have a set of clinical trials that prove that screening women of that age group will reduce mortality. The Swedish trial you referred to, Representative Brown, the Gothenberg trial, are preliminary results. I assure you that if that trial proves a significant mortality reduction, then we will revisit the issue in a scientific way. There is absolutely no question about that. And I want to emphasize that our decision, and our statement, has absolutely nothing to do with the cost of mammography—absolutely nothing. Our path toward this, including the review committees that we convened, meetings and so forth, was set well before health care reform was a gleam in anybody's eye. The conclusions that we are stating were drawn by a scientific group that has no issue with respect to reform.

Mr. BROWN. Dr. Sondik, what is the risk of a 31 year old woman in my office getting a mammogram or my daughters when they turn 30—what is the risk of—I mean if it were some sort of treatment that might cause them other serious illness, I would understand NCI's holding back on this, their restraint. But what is the risk of a 30 year old woman or a 35 year old woman or a 40 year old woman getting a mammogram?

Mr. SONDIK. I think that is an excellent question. In fact, that is the issue. If there is no down-side, if you will, associated with this, then why not have it.

Mr. BROWN. Except for the $85.

Mr. SONDIK. Yes. The mammography will reduce mortality 30 to 35 percent in women 50 and over, is not a particularly effective technology in terms of its precision. The rate of false negatives for women over 50 is perhaps 25 percent. That is, if you do have breast cancer and you have this test and the results are negative, you should absolutely not feel that everything is clear. If there is any sign or symptom that you should see within the next several months, see a physician immediately. This is absolutely essential, because there is a significant error rate. The error rate for women in their 40's is 40 percent. In other words, 40 percent of the time, it is going to miss a cancer if it is there. Some place between 2 and 5 percent of the time, mammography will indicate that there is a cancer, which will require further testing, when in fact it is not there. And that rate is uniform across all age groups.

So if one were to apply mammography for women in their 30's, there really at this point are no groups that I know of that are recommending mammography. Although there is no question that mammography in a rare situation will pick up a cancer for a woman in her 30's, we have no evidence that the application of it on a population-wide basis would influence the mortality statistics.

So the down-sides are as follows: First, there is a significant error which could lead to ignoring signs and symptoms when they occur. It could lead to significant morbidity from further testing when in fact no resultant change in mortality would occur. And finally—and I need to say this carefully—there is a radiation risk associated with it, although it is extremely small. But there are no experts that I know of, including experts in the radiology community, that are recommending that mammography begin early because the earlier you begin, the more cumulative effect you have of this. We are dealing with radiation that is on the order of a chest x ray. And if one does not need to do it, then there is a question of whether one should do it. So that is part of the issue. There also is some experimental evidence, not proven, that there is a very small group of young, pre-menopausal women who are particularly susceptible to this type of radiation. We do not know how to identify that group. It is more a question of theory at this point than it is actually proven, but there is some possibility that there is such a group in whom the radiation could in fact cause breast cancer. In other words, the mammography could cause this. We think that group is small, but we cannot identify it at this point.

So one needs to be circumspect in using this. And again, if a woman looks at these statistics, if she has breast cancer in her family, if she is particularly concerned about it and she knows these risks and she feels she should have it, then I would endorse her having it. If she feels she does not want to have it, then I would say that is her decision. Certainly though when a woman turns 50, at that point, we have the evidence that proves that it will reduce mortality. And to not have regular mammography at that age is, I think, throwing away an opportunity to greatly improve your chances of dealing with breast cancer.

Mr. BROWN. There is, Dr. Sondik, a new test for prostate cancer that is a blood test, is my understanding. More than a few women have said to me that if breast cancer were a male disease, there would be a blood test for breast cancer. Is that a reasonable statement, number one. And number two, is there anything close to that, a non-invasive, non-radioactive, if you will, test being developed or researched or imminent?

Mr. SONDIK. Yes, it is certainly being researched. One of the principal possibilities here is the so-called BRCA-1 gene. The identification of that gene and then the development of a test that would identify it, would indicate familial risk of breast cancer. In other words, that form of breast cancer that runs strongly in families, and particularly affects young pre-menopausal women.

There is research underway toward developing blood tests, but nothing is in the position of the prostate-specific antigen test, which exists for prostate cancer. Just let me point out something about the prostate-specific antigen test. The mortality associated with a prostatectomy is on the order of 1 percent. There have been studies that have indicated that the widespread use of this test as a screening device could, in fact, lead to more mortality than it would save because of the high level of mortality associated with the primary operation. So it is very important that anyone who applies this consider again multiple opinions and be very circumspect in its use.

Mr. BROWN. Thank you, Dr. Sondik.

Dr. Obrams, I have noted with interest your Long Island study and how it includes concerns about pesticides and herbicides due to the fact that Long Island still, on the eastern end, and overall, is and was an agricultural area. As we mentioned earlier, Medina County, an area that is recently very agricultural and still pretty agricultural in northeast Ohio, has experienced, according to State Health Department numbers, a very high incidence of cancer. Also the GAO showed the Great Lakes, including Lake Erie obviously, are very sensitive to the effects of those herbicide/pesticide agricultural pollutants. The retention time for pollution in Lake Erie seems to be higher than many other bodies of water because less than 1 percent of the water flows out of the lakes annually, which means some of those pollutants can settle into the bottom of the lake and be stirred up, and those pesticides, as they accumulate in sediments will be mixed back into the water, and bio-accumulate in the food chain, it is my understanding.

Tell us, if you would, a little bit more about pesticide and herbicide risk in Long Island, what that might mean to northeast Ohio in conjunction with the lake and in conjunction with direct—directly in the soil in agriculture, please.

Ms. OBRAMS. We are actually at a very exciting time right now in terms of what we can accomplish, both through biological research and through the use of biological techniques and epidemiological and population-based research. We are reaching a point in time now where we are sharpening and refining our tools for measuring both current exposures to us as individuals and to past exposures, say to a body burden of exposure, in ourselves and in the men and women that we need to study. In the Long Island project and in the related projects that we are also coordinating throughout the northeast, we are focusing very much on standardizing and validating ways to identify an individual's past exposure, either to pesticides on lawns, to herbicides along roadsides, to run-off of these chemicals into the water supply. In Long Island, that is particularly critical because of the shallow aquifer and the use of well water by everyone in Nassau and Suffolk Counties. But Long Island is by no means unique in that particular characteristic, nor in concerns about the water.

And so our particular push and our big hurry is to be able to develop blood tests and potentially also analyses of the fat, and to compare the two, to see if we can identify for any given individual what their past exposure history might have been. We could then correlate that, hopefully, with health effects—now breast cancer and possibly other health effects. So I think we will be able to make an important contribution to learning about these things for everyone raising this question.

Mr. BROWN. Thank you.

Dr. de Freitas, I noted with interest in your written testimony about the use of work site health promotions to provide both prostate and breast cancer screening in the workplace. It is clear that is a very effective tool. On the subcommittee, I have been working to include that in whatever the health care bill that ultimately passes is, to include a work site health promotion component.

Would you elaborate on the availability of these services and the response of employers and employees to the use of the screening for prostate and breast cancer?

Mr. DE FREITAS. I have done one on prostate and Dr. Laing has been very much involved with setting these up at one local industry. It has worked very well because in the males, we must have gone through in 2 days I guess about 150 men. We did the rectal examinations privately in a small room, we had literature, we drew at the same time the PSA's. And that worked very well. We did not get any cancers. We had I think four elevated PSA's, but no cancers were proven. Not all of them had been biopsied but those four went to ultrasonography.

In breast, I think you would probably have to have spouses bring their wives in to the workplace and it could be done the same way. Mammography can be done by a mobile unit, which in this case was placed right on the lawn outside of the health office. And I think it was over 2 days, women were able to get both a mammogram and a physical examination. In that case, my recollection is that there was one cancer that was picked up. And I think we were dealing with about 100, under 150 women. Now granted, that one picked up was a woman who would have been picked up by physical examination without mammogram, but you still would not have picked her up unless you screened her. So I think you need both.

Ms. McGreer made a very eloquent point about what Dr. Sondik said about negative mammograms. A dimpling of the skin or a mass equals cancer until proven otherwise. You had better be sure that is not a cyst, you had better do ultrasonography if that is a dense breast. Otherwise, there are dire consequences both medically and legally. So I think that I am very much in favor of screening in the workplace. I think it should be able to work very well.

Mr. BROWN. Several occupational nurses have told me that they have viewed—through their work site health promotion activities, they have encouraged—used those programs to educate women about self-examination. Is that something that you are leading into doing?

Mr. DE FREITAS. There are three parts to screening. One is education, probably the most important, because breast self-exam, of the triad, is probably the most important. The next is mammography and the third is annual screening by someone, a health professional, once a year. I agree with mammography at age 35 as a baseline, depending on family history. If your mother had breast cancer pre-menopausal, then you probably alter your guidelines. But those three are absolutely essential and they have to be repeated, and you have to give out literature. My office is filled with literature. My problem is that many patients just do not read it. So I think you have to do it on a one-to-one basis, and the nurse in the work site very often can do that. It does not have to be a physician who feels the breast; it can be a health care professional like a nurse practitioner. And in fact, they will probably be getting better than us, because they will be feeling a lot more breasts in one day than physicians do. So we are going to depend heavily on them.

The key part about mammography—I do not want to belabor this—is that if you find something on mammography, the cure rate is very high. This is why in situ cancers have shot up and the cure rate could be virtually 98 percent with in situ cancers. Where does it occur? It is like cancer of the cervix, it occurs earlier than 50. So therefore, to exclude the woman who may be developing cancer—here this morning we are arguing about the incidence doing this, so this contradictory message I think is the point that is very disappointing, because women are interpreting this as saying—they may leave this room saying that well mammography is not that good, there is a 40 percent error. They must not be very good in Bethesda, because I have never heard that figure of 40 percent error in mammography, in screening mammography. You could improve that by having two mammographers read your mammogram, which is what I would recommend if you are getting 40 percent inaccurate reading.

Mr. BROWN. Thank you.

Dr. Schulte, you made a pretty clear case at the beginning of your written testimony that estrogen plays a significant role in development of breast cancer. Would you comment on the potential impact of oral contraceptives and linked to breast cancer and women in later life using estrogen? Would you comment—I asked Dr. Sondik a similar question—if you would expand on that.

Mr. SCHULTE. Certainly in the literature on the role of estrogen, endogenous estrogen and exogenous estrogen, we have seen that there can be effects on the estrogen levels that could be of concern. However, I am most comfortable talking with the occupational sources of estrogen. I could get you some information on oral contraceptive replacement therapy, but I would rather just comment about occupational sources at this point.

There are things in the environment that could add to therapeutic estrogen; add to the impact of therapeutic estrogen. So when we do research, I think we need to look at the total picture rather than just to look at therapeutic or look at occupational sources. We need to look at the total amount of factors that could modulate estrogen in a woman, and do our risk calculations and our research based on that total picture.

Mr. BROWN. You noted your study of exposure to ethylene oxide and the increased risk of breast cancer around that. Are you aware of industries which may be in northeast Ohio that emit ethylene oxide that could be potentially dangerous here?

Mr. SCHULTE. The formation of mammary tumors after ethylene oxide exposure was in laboratory animals. We hope to assess that hypothesis in workers wherever ethylene oxide is used, that would be a target population that we would be interested in studying. It is certainly used in hospitals and we have done a study—it was not aimed at breast cancer, but we and other researchers have identified that at the current levels of exposure, there are changes in chromosomes in people who have had ethylene oxide exposure. Whether or not that says to us anything about risk for breast cancer is still a question. That is why we have assembled for study the group that we have.

I do not know particularly of any specific sources in northeastern Ohio.

Mr. BROWN. Well what kind of industries is—ethylene oxide is a byproduct in what kind of industries?

Mr. SCHULTE. Well its major use is as a sterilant. It is used to sterilize instruments in hospitals. It is used to sterilize—in the commercial sterilization industry—it is used to sterilize larger hospital equipment and spices and various products for consumption. So it is a narrow industry, except for the wide use in hospitals. We estimated I think around 100,000 people in the United States were exposed to ethylene oxide.

Mr. BROWN. Last question, Dr. Schulte, what other chemicals do you believe we need to investigate for potential links to breast cancer?

Mr. SCHULTE. I think one candidate group of chemicals is the polycyclic aromatic hydrocarbons. There is a literature that shows some effects in animals and I think they are quite ubiquitous. They occur during the combustion of a lot of organic materials—I think they would be candidates as well as further work on organo-chlorine containing compounds. Those would be my two candidates.

Mr. BROWN. It amazed me to hear you say at the beginning that we have—you know, we have looked at other factors and have not really looked enough at environmental factors. We have looked at hormonal factors, and it just seems obvious, as a non-scientist—maybe that means my credibility is not too great—but it is pretty obvious to me when you look at geography and if you see that Long Island has a high rate or northeast Ohio has a high rate, that there is something there beyond hormonal. I mean, I do not know if it agricultural, I do not know if it is an industrial plant, but I just think that is an obvious avenue to go down, Dr. Sondik.

Mr. SONDIK. I completely agree with you on that. And I think one of the points to remember in this is that we have learned so much over the last 20 years or so that the kinds of studies that we can do now, the kinds of tests that can be done looking for particular types of chemicals deposited in the body, such as the Mary Wolff study that was done on the DDT residue, were not possible years ago. But we can do them today and I think this is part of this renewed interest in looking at these particular factors. We now have a population in Triana, which is part of Alabama, which has been exposed to a DDT spill, a very, very heavily exposed population, and they have been exposed for years, it turns out. We are now able to study them and we are doing that. And that should add tremendously to the body of knowledge that we have about this.

But your point about these geographic and environmental correlations I think is very well taken and it needs to be and is being pursued.

Mr. BROWN. Dr. Schulte.

Mr. SCHULTE. I concur. I think the telling statistic is the one that we have heard from a number of people—Dr. Sondik said 30 to 70 percent of breast cancer is explained by the known, mostly the hormonal risk factors. So that means that as much as 30 to 70 percent is not explained. Certainly that is why I am in the occupational epidemiology business. I look for congregations of cases according to workplace or according to geography. That is why I would support investigations and more research in that regard.

Mr. BROWN. Dr. Sondik, I have one brief series of questions and then we will conclude.

I was part of the Oversight Committee on the NSABP tamoxifen issue and want to just ask you some questions. I hear concerns from women that I met with on Saturday that were part of that trial and I wanted to just make sure that things are clear for them and for all of us about this. There continues to be a lack of understanding about what is happening to the women participating in the trial nationwide, and whether new participants will continue to be recruited. It is my understanding that women who are currently participating in the tamoxifen prevention trial will continue to be followed, correct?

Mr. SONDIK. Absolutely.

Mr. BROWN. No change there. And while NSABP was temporarily suspended from recruiting new women into the trial because of the problems with the study and with the data, that preliminary measures are currently being taken so that NSABP will again be recruiting new women to the trial?

Mr. SONDIK. That is correct. In fact, they are doing risk assessments now, which is the first part of the recruitment process. If it turns out that the risk is at the right level, the appropriate level, then the woman can be admitted into the trial. The problem that we had with this had to do with the data quality control procedures—quality assurance procedures. The tamoxifen trial was not impacted greatly by that, but there was an instance in which something was affected, and we felt that the best thing that we could do was to hold back while we—with the help of NSABP and the University of Pittsburgh—worked to fix the system, if you will, both at the NSABP and also at the NCI. And I think we are back on track now.

Mr. BROWN. The last question about that. In light of the problems in both Pittsburgh and in Montreal, NCI is not considering throwing away the information that tamoxifen obtained from these trials, or scrapping the trial entirely, correct?

Mr. SONDIK. We are not; you are absolutely correct. We are moving forward. We consider this one of the most important activities that we have underway and we are doing everything we can to have it move forward and be successful.

Mr. BROWN. OK, thank you for testifying, all four of you—thanks.

Thank you all, all three panels, for joining us. Thank you also for people in the community that have come to hear us today and to discuss all of this with us, and most importantly to give us additional input. I would reiterate that any information that any—if any of you would like to submit written testimony, we would be glad to accept that and enter it into the record, and include that in our entire data bank and be able to have useful information certainly from that. Also, there are forms outside, if you would like to have comments or have questions, address questions to me or to the committee.

This hearing clearly provided a good deal of worthwhile information. It also, unfortunately, demonstrates how much more information we need. I hope that this hearing will—the information we gather in this hearing will contribute ultimately to the health care bill that we pass this year, if in fact we pass a health care bill, particularly in what physician choice and the ability for women and men to go to the doctor whom they choose, and to be able to get the kind of medical care that they deserve.

For physicians and public health practitioners and cancer experts, I would particularly ask them to listen to women that testified today, listen to women who are their patients, listen to women that are cancer survivors and the kind of information that they can provide.

My eyes were opened in the last month or two, when I hear things such as the first studies on breast cancer were conducted on men, when I heard that many people in their 60's and 70's take an aspirin a day I guess to dilute their blood and to be able to fend off heart disease. The study that put that whole phenomenon in motion, if you will, that practice in motion, was done only on men, not on men and women. So just the kind of—the way that this health care system and the way the society has failed in providing for better information and better studies on women's health is something I hope this subcommittee can do something about and that we can move forward on.

And last, I would like to sum up what Ms. McGreer said, who said it better than anybody, that her three fingers, her eyes and her spirit is what saved her life. And I would hope that message would get out to women and women that might some day have breast cancer. It is certainly going to get out to my daughters who are very young, but are, as every other woman, potentially exposed to this.

I again thank you all for coming. Anyone that wants copies of tapes of the hearing can get them from St. Joseph's and I again particularly thank them, thank Chairman Waxman, who obviously is more important in Washington than I am, because he has got to go and I can stay here for a couple more hours. And I will be around. My plane is not until 3:20. I have votes this afternoon, but I will be around until probably 2:30, 2:45, to just talk to any of you or take questions or whatever you want to do informally.

Thank you very much.

[Whereupon, at 12:11 p.m., the hearing was adjourned.]

[The following statements and letters were submitted for the record:]

STATEMENT OF ANDREA VLOCK AXEL

My name is Andrea Vlock Axel. I am a thirty-three year old wife, mother and breast cancer survivor. I was diagnosed with breast cancer on February 26, 1993 at the age of thirty-two. My daughter had just turned seven and my twins were about to celebrate their fourth birthday in March. Why did I develop breast cancer at such a young age? Although I may have had a genetic predisposition toward the disease, I believe there were other factors involved.

I was born in New York City on September 20, 1960. In 1963 my family moved to Gloversville, a small city in upstate New York. Gloversville is most well known for its glove factories and tanneries. I am not familiar with the glove making process, but from the smell of the tanneries I would guess that there are toxic chemicals involved. Were some of these chemicals released into the water or soil to be absorbed by the residents of the city? I am hoping that the breast cancer rate in Gloversville will be studied to see if there is an increased rate of the disease there also.

After graduating from high school in 1978 I enrolled at Cornell University. I graduated from Cornell with a degree in psychology in 1982 and moved to the greater Cleveland area. I married my husband in 1983 and received a Master's degree in deaf education in 1984. Our first child was born in January 1986 and our twins were born in March of 1989. The first pregnancy and birth was normal and uncomplicated. The second pregnancy resulted in some complications common to twin pregnancies and I was put on medication and bed rest to prevent premature labor. All three children were born healthy.

At the beginning of February last year I was doing my monthly breast examination when I found a large lump—a lump that had not been there a day ago, much less a month ago. I was certain that it would be benign because of my age. I called my gynecologist who saw me the next day. He felt it was also benign, but referred me to a specialist just to be cautious. I saw my breast surgeon on February 26, 1993 at which time he performed a needle biopsy. The results of the biopsy showed that the lump was malignant. The shock that I experienced is indescribable. My doctor prescribed a mild tranquilizer so that I could sleep and get on with my daily life. The added horror of my situation was that we had just gone through the diagnosis and treatment of my father's prostate cancer (he is now healthy with no sign of disease) and the death of his younger brother from bladder cancer. I am grateful that both my father and I have had cancers that are treatable and curable.

On March 8, my twins' birthday, I went into the hospital for a lumpectomy and axillary dissection (removal of the lymph nodes.) My surgeon had also found a second malignancy in the same breast, so I then opted for a mastectomy in order to make sure that all the cancer was removed. Most of my friends were pregnant or having babies at the same time that I was in the hospital having a breast removed due to cancer. I felt like my life had been taken from me. I was still at a childbearing age, yet I did not know if I would live to see the children I did have grow up.

After my two surgeries I underwent three months of chemotherapy. I received Adriamycin and Cytoxin—drugs not only strong enough to kill any remaining cancer cells, but strong enough to cause vomiting and sores to form inside my mouth. Two weeks after my first treatment my hair started to fall out. Imagine taking a shower and being unable to wash your hair because handfuls would come out when you tried to put shampoo in. Imagine being unable to eat a meal without hair falling onto your plate as you take a forkful of food. Imagine having to call a friend to come over and wash most of your hair down the drain because you just cannot stand having it fall out all over the place. I don't have to imagine any of these things, because I lived them. Chemotherapy is the horror you have read about in the media or seen on television movies, except that when you are the person living the nightmare you can't close the book, turn off the television or even wake up. You live it twenty-four hours a day.

I have spent many hours questioning why I developed breast cancer—questions that will probably never be answered. I hope that a vaccine will be developed that will prevent other women from having to live this nightmare. I hope that by the time my two daughters are grown women this disease will be conquered.

ALFRED A. RIMM, Ph.D.

MEMBER OF BOARD OF TRUSTEES

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Breast cancer is one of the most devastating diseases known to mankind. More than 35,000 women each year die of breast cancer in the United States. This human toll each year during the past twenty years has resulted in the emergence of two large biomedical research communities to find a solution to this disease. One of these communities is made up of scientists and clinicians who are trying to develop a cure for the disease using various forms of therapy such as drugs, radiation and surgical techniques. The other community of scientists are those who are searching for factors that cause disease.

The success of the treatment for breast cancer has a lot to do with the stage of the disease when it is first diagnosed. Women who have early stage of disease have a 90 percent chance of a surviving five years. Those women with a very late stage of disease at diagnosis have only a 20 - 30 percent of five year survival. Unfortunately, the success of various treatment regimens have not changed over the past 10 years. As a result, deaths from breast cancer are at approximately the same level as they were 10 to 15 years ago.

Those scientists who have spent their lives searching for the causes of breast cancer have turned up a number of factors that are associated with the disease. Table 1 which has been reproduced from a research journal entitled Epidemiological Reviews, (Vol. 15, No. 1, 1993 entitled "Breast Cancer"; edited by Jennifer Kellsey) shows the risk factors for breast cancer. The Table shows the persons in the high risk and the low risk groups, for example, age is a risk factor, the older you get the higher the risk of breast cancer. The risk greater than 4, as shown in the table, means that if you compare young women to older women, the older women have four times the incidence of breast cancer than young women. Another example, is the country of birth; breast cancer is very high in North America and Northern Europe, whereas very low in Asia and Africa

The concern for finding the causes of cancer is demonstrated by the fact that the Center for Disease Control in Atlanta, Georgia, receives calls from thousands of persons each year asking questions about a cancer cluster in their neighborhoods. The question usually is: Could there possibly be an agent in the environment causing the cluster? Almost all of these requests lead to no definitive answer. Scientists working in the field of breast cancer etiology for the past 20 years have conducted literally hundreds if not thousands of studies to try to uncover new causes of breast cancer. With the exception of those listed above, no new risk factors for breast cancer have been uncovered. Another problem in determining causes of breast cancer is that large groups of women are needed to discover a new etiologic agent. If one were discovered, most scientists would not act on it until other large epidemiological studies confirm the original results A good example of this is cigarette smoking and breast cancer. At the present time, there are 32 studies in the biomedical research literature investigating the relationship between cigarette smoking and breast cancer. Not one of these studies shows a relationship between the two.

The scientists who study causes of breast cancer are epidemiologists. They have formed a special society to exchange ideas and meet on an annual basis to discuss possible new etiologic agents in breast cancer. For example, this past year there was a meeting in June of the Society of Epidemiological Research with a meeting devoted to casual agents in breast cancer. No new agents or risk factors were shown to be on the horizon. We should recognize that hundreds of scientists have dedicated their lives to finding causes of breast cancer. Day in and day out they think about the problem and investigate any possible lead. This enormous effort has supplied us with the risk factors shown in Table 1. Unfortunately we cannot do anything about many of these risk factors.

Recent work in the Department of Epidemiology and Biostatistics at CWRU may be relevant to discussions concerning breast cancer in Northeast Ohio The Cancer Data System of the Greater Cleveland Hospital Association has been sponsoring and operating a population-based tumor registry. This is an established registry with reporting of every cancer in the County. The data from this registry were used to calculate incidents rates of cancer in Cuyahoga County. These rates were compared to the incidents rates from other large cities in the United States with population based cancer registries. Figure 1 shows the incidents rates for Cuyahoga County for both black and white women adjusted for age for the period 1987 - 1989. Compared to the average, age adjusted incidents rates for the U.S. blacks and whites we can see that the rates for Cuyahoga County are slightly higher. Whether in fact this is a random fluctuation because only three years of data where available, will only be known when more data is collected by the tumor registry Furthermore, one can see that the Cuyahoga County rate for blacks and whites are below that for San Francisco.

In the study of the entire U.S. population above the age of 65 where approximately

60 percent of breast cancers occur, the faculty at CWRU studied the distribution of breast cancer in the U.S. for the year 1989. Figure 2 shows the areas of high and low incidence. It is generally known that the highest risk of breast cancer occurs in the Northeast U.S. and in Michigan, Minnesota, Wisconsin and California. When a similar map is made of Ohio, (Figure 3) the incidence rates for counties may have happened by random chance. What this map of Ohio also shows is that there does not seem to be a concentration of tumors in older women along the Lake Erie shoreline.

In summary, the problem of identifying risk factors for breast cancer is very difficult and hundreds of scientists in the U.S. have dedicated their lives to uncover the causes. The data from Cuyahoga County shows that the incidence rates, though slightly higher than the national average, are in the same neighborhood as other large metropolitan areas. The national average incidence rates based upon the national (SEER) registries includes rural areas which have lower rates, thus lowering the average.

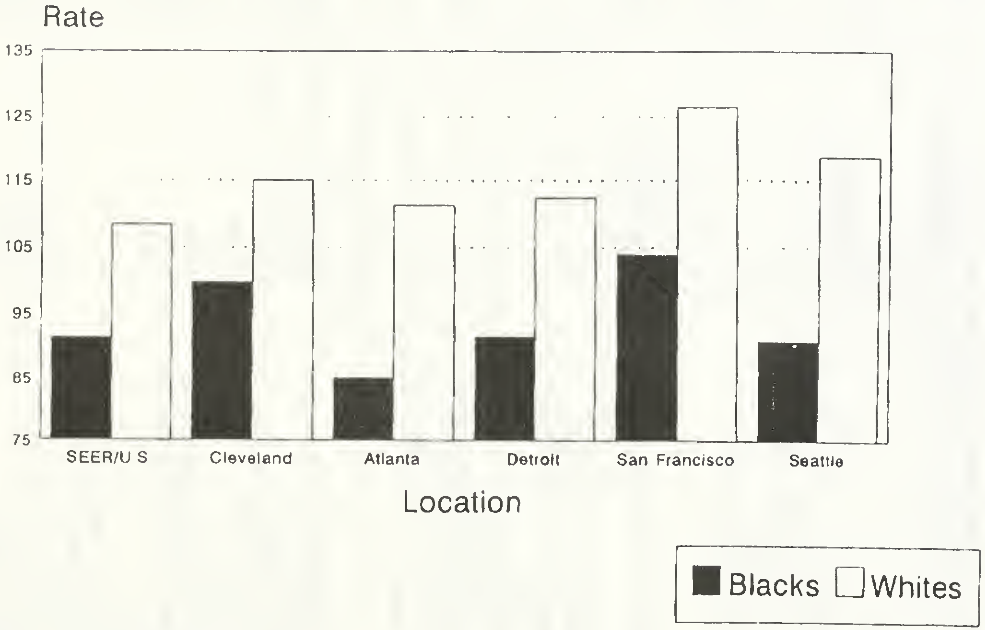
The difficulty of finding a new cause of breast cancer from a cluster of cases is highly unlikely, mainly because other reports of clusters have not resulted in new causes of breast cancer. It is a deadly, elusive disease and many scientist have devoted their lives to it.

TABLE 1. Established risk factors for breast cancer in women

Factor	High-risk group	Low-risk group
	Relative risk > 4.0	
Age	Old	Young
Country of birth	North America, Northern Europe	Asia, Africa
Mother and sister with history of breast cancer, especially if diagnosed at an early age	Yes	No
Atypical epithelial cells in nipple aspirate fluid	Yes	No fluid produced
	Relative risk = 2.1–4.0	
Nodular densities on the mammogram	Densities occupying >75% of breast volume	Parenchyma composed entirely of fat
History of cancer in one breast	Yes	No
Mother or sister with history of breast cancer	Yes	No
Biopsy-confirmed benign proliferative breast disease	Yes	No
Hyperplastic epithelial cells without atypia in nipple aspirate fluid	Yes	No fluid produced
Radiation to chest in moderate to high doses	Yes	No
	Relative risk = 1.1–2.0	
Socioeconomic status	High	Low
Marital status	Never married	Ever married
Place of residence	Urban	Rural
Place of residence (within United States)	Northern	Southern
Race/ethnicity		
Breast cancer at ≥45 years of age	White	Hispanic, Asian
Breast cancer at <40 years of age	Black	Hispanic, Asian
Religion	Jewish	Seventh-day Adventist, Mormon
Removal of ovaries before age 40	No	Yes
Nulliparity, breast cancer at ≥40 years of age	Yes	No
Age at first full-term pregnancy	≥30 years	<20 years
Age at menarche	≤11 years	≥15 years
Age at menopause	≥55 years	<45 years
History of primary cancer in endometrium, ovary	Yes	No
Obesity		
Breast cancer at ≥50 years of age	Obese	Thin
Breast cancer at <50 years of age	Thin	Obese

Figure 1

BREAST CANCER IN WOMEN



Incidence: Rate/100,000

Figure 2

Atlas of White Female Breast Cancer In 1989 for Medicare Population
65 Years and Older(Age Adjusted Rate/10,000)

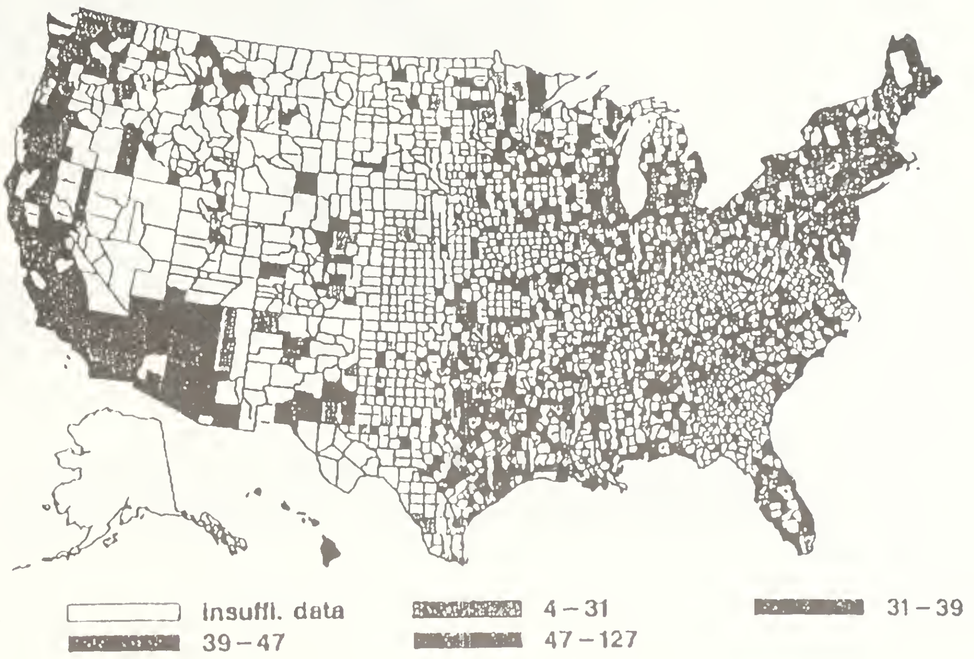
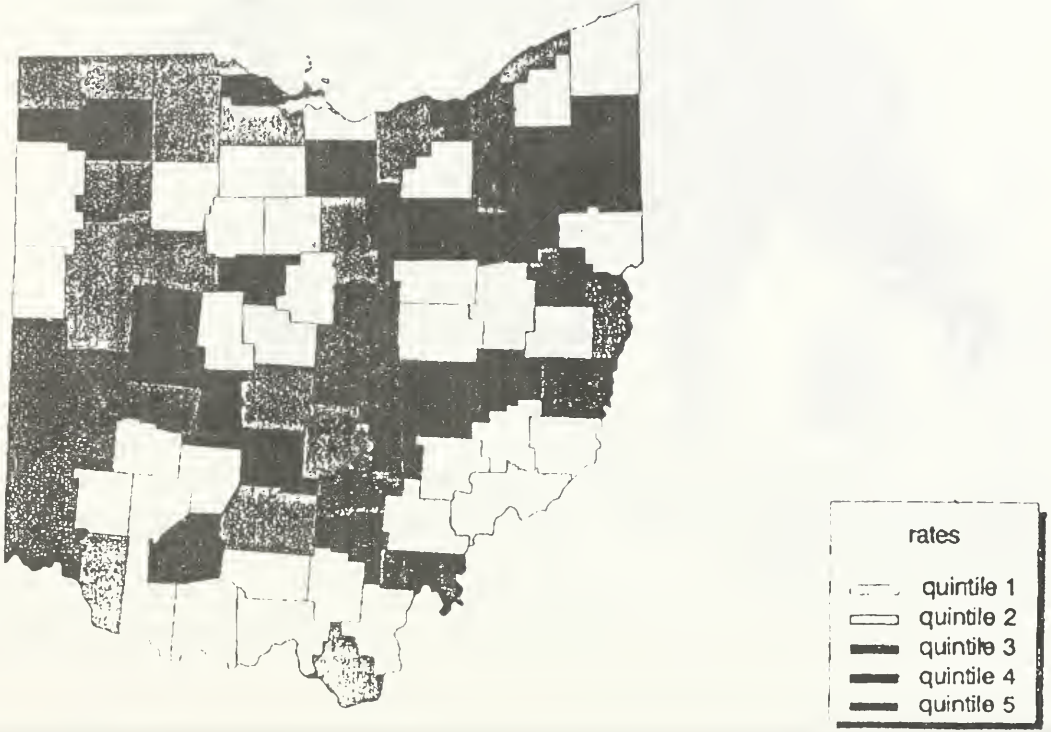


Figure 3

Female Breast Cancer in 1989 for Medicare Population
65 Years and Older (Age Adjusted Rate/10,000)



July 22, 1994

Memo To Congressman Sherrod Brown
From John W. Gofman, M.D., Ph.D.

Dear Congressman Brown:

Greetings from an original Ohioan. I grew up in Cleveland, Ohio, and got my bachelor's in Chemistry from Oberlin College, so close to Lorain.

It has come to my attention through the alertness of Ms. Connie Kline of Willoughby Hills, Ohio that Northeast Ohio feels it is in the throes of a special breast cancer epidemic. Being an Ohioan, and being deep into research on the cause of breast cancer, I am offering some testimony (attached) for your hearing on this matter of breast cancer.

I think it is fine to look for accelerators of breast cancer, such as may be the case for pesticides, e.g. organochlorines, but I believe this may divert you from the one PROVEN somatic cause of breast cancer, ionizing radiation. We have a very good estimate of exactly how important ionizing radiation is in the causation of breast cancer.

THE GOOD NEWS:
BREAST CANCER IS DEFINITELY A PREVENTABLE DISEASE, TO A VERY LARGE EXTENT.

THE BAD NEWS:
A DETERMINED EFFORT SEEMS TO BE MADE TO OBSCURE THESE FACTS FROM WOMEN.

I note in an article on this subject, your staff member, Mary McSorley, has stated, about women in Lorain, that "They just wanted to know why" [so many women in the area have breast cancer], and "they want to know how to protect their daughters."

Unless serious attention is given to this matter (as explained in the testimony attached), I can say to Mary McSorley that about 182,000 American women are going to continue to develop breast cancer per year in America and I can say their daughters' fate will be no better.

Sincerely yours,

John W Gofman

John W. Gofman, M.D., Ph.D.
Professor Emeritus, Molecular and Cell Biology
University of California at Berkeley
Berkeley, California 94720
Chair, Committee for Nuclear Responsibility

Mailing Address
P.O. Box 421993
San Francisco, Ca. 94142

Fax: 415-664-1933
Phone: Same as fax

estimate (from evidence available) what dose of radiation to the breast was received PER YEAR by women of all ages up through 64 years in the period 1920–1960, and from this I shall estimate the expected number of breast cancers in 1970 --- a point thirty years after the midpoint of 1920–1960.

V. I am really estimating the MINIMUM exposure to ionizing radiation, since many sources cannot yet be accounted for. Therefore, I do not think I am exaggerating any of the expectations of breast cancer.

VI. The breast cancer incidence for 1970 was 68,000 per year. My estimate, at this stage of analysis, is 61,000. Therefore, I necessarily conclude that a very large share of breast cancers is caused by ionizing radiation. The uncertainties in measurement would not permit saying that VIRTUALLY ALL breast cancers are caused by ionizing radiation, but that is a possibility. And I should point out that accelerators of breast cancer can act together with (in synergy with) ionizing radiation.

VII. Given the status of these calculations, it is reasonable to recommend that all sources of unnecessary ionizing radiation, FROM BIRTH ON, should be drastically restricted ---- if anyone is serious about starting the prevention effort with respect to breast cancer.

VIII. If women look around themselves and see how little has been done to make all this evident, they will come to realize that prevention of breast cancer will come from the bottom up, not from the top down.

(This is a synopsis of a very lengthy quantitative report being prepared on the subject of Breast Cancer Causation, to be published in a few months.)

Meanwhile, Congressman Sherrod Brown, I applaud your efforts to bring this issue to the fore in Lorain. While I cannot attend your hearings, I can assure you of my continuing concern. When my complete paper is written, I will make it available to you, perhaps for the Congressional Reocrd of your Hearings.

John W. Gofman

John W. Gofman, M.D., Ph.D.
July 22 ,1994

LORAIN COUNTY
COMMISSIONERS

Commissioners

Herbert J. Jacoby
Mary Jo Vasi
E.C. (Betty) Blair

July 27, 1994

Congressman Sherrod Brown
United States Representative
Allen, Thorley, DeLloyd Building
5201 Abbe Road, 2nd Floor
Elyria, OH 44035

Dear Sherrod:

Thank you for the invitation to participate in the discussion hearing Saturday, July 30, 1994. The issue should not just be breast cancer, but cancer as a whole.

The U. S. Environmental Protection Agency has identified 366 chemicals as extremely hazardous. The most common, extremely hazardous chemicals are ammonia and chlorine.

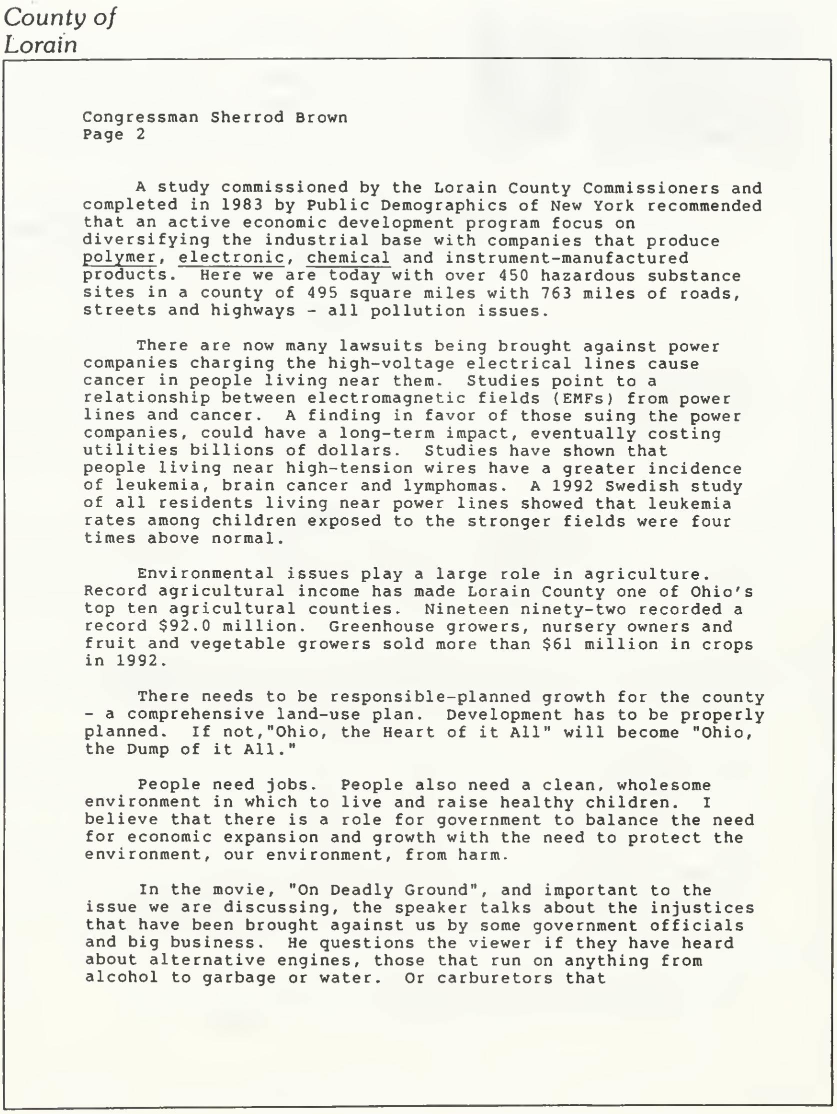
Lorain County businesses are to report their stores of hazardous chemicals to the Lorain County Emergency Management Agency. In all, 375 hazardous substance sites and 62 extremely hazardous locations have been reported to the county. Richard Roman, Director of the Lorain County Emergency Services Department, said 30% to 40% of the businesses in Lorain County that should report their stores of chemicals have failed to do so.

Keep in mind that water treatment plants, farmers, schools and government agencies do not have to report chemicals (materials such as janitorial supplies, etc.).

What happens when the chemicals are released through smokestacks, combine in the air and come back down mixed with emissions pollution, chemicals used on farms, etc.? There is no guessing, in my opinion, that if this is allowed to continue, we are not only killing the earth, but society as well, from the food we eat, the water we drink to the air we breathe.

Will the truth be revealed, or will the government allow this to continue in the name of economic development (jobs)? The right to know must take affect.

Administration Building, 226 Middle Ave, Elyria, OH 44035-5641 • Phone: (216) 329-5000 or 244-6261 • Fax: (216) 323-3357



A study commissioned by the Lorain County Commissioners and completed in 1983 by Public Demographics of New York recommended that an active economic development program focus on diversifying the industrial base with companies that produce polymer, electronic, chemical and instrument-manufactured products. Here we are today with over 450 hazardous substance sites in a county of 495 square miles with 763 miles of roads, streets and highways - all pollution issues.

There are now many lawsuits being brought against power companies charging the high-voltage electrical lines cause cancer in people living near them. Studies point to a relationship between electromagnetic fields (EMFs) from power lines and cancer. A finding in favor of those suing the power companies, could have a long-term impact, eventually costing utilities billions of dollars. Studies have shown that people living near high-tension wires have a greater incidence of leukemia, brain cancer and lymphomas. A 1992 Swedish study of all residents living near power lines showed that leukemia rates among children exposed to the stronger fields were four times above normal.

Environmental issues play a large role in agriculture. Record agricultural income has made Lorain County one of Ohio's top ten agricultural counties. Nineteen ninety-two recorded a record $92.0 million. Greenhouse growers, nursery owners and fruit and vegetable growers sold more than $61 million in crops in 1992.

There needs to be responsible-planned growth for the county - a comprehensive land-use plan. Development has to be properly planned. If not,"Ohio, the Heart of it All" will become "Ohio, the Dump of it All."

People need jobs. People also need a clean, wholesome environment in which to live and raise healthy children. I believe that there is a role for government to balance the need for economic expansion and growth with the need to protect the environment, our environment, from harm.

In the movie, "On Deadly Ground", and important to the issue we are discussing, the speaker talks about the injustices that have been brought against us by some government officials and big business. He questions the viewer if they have heard about alternative engines, those that run on anything from alcohol to garbage or water. Or carburetors that

County of
Lorain

can get hundreds of miles to the gallon, or electric or magnetic engines that can practically run forever. He explains that we haven't heard about them because if they were to come into use, they'd put the oil companies out of business. The concept of the internal combustion engine has been obsolete for over 50 years, but because of the oil cartels and corrupt government regulation, we and the rest of the world have been forced to use gasoline for over 100 years.

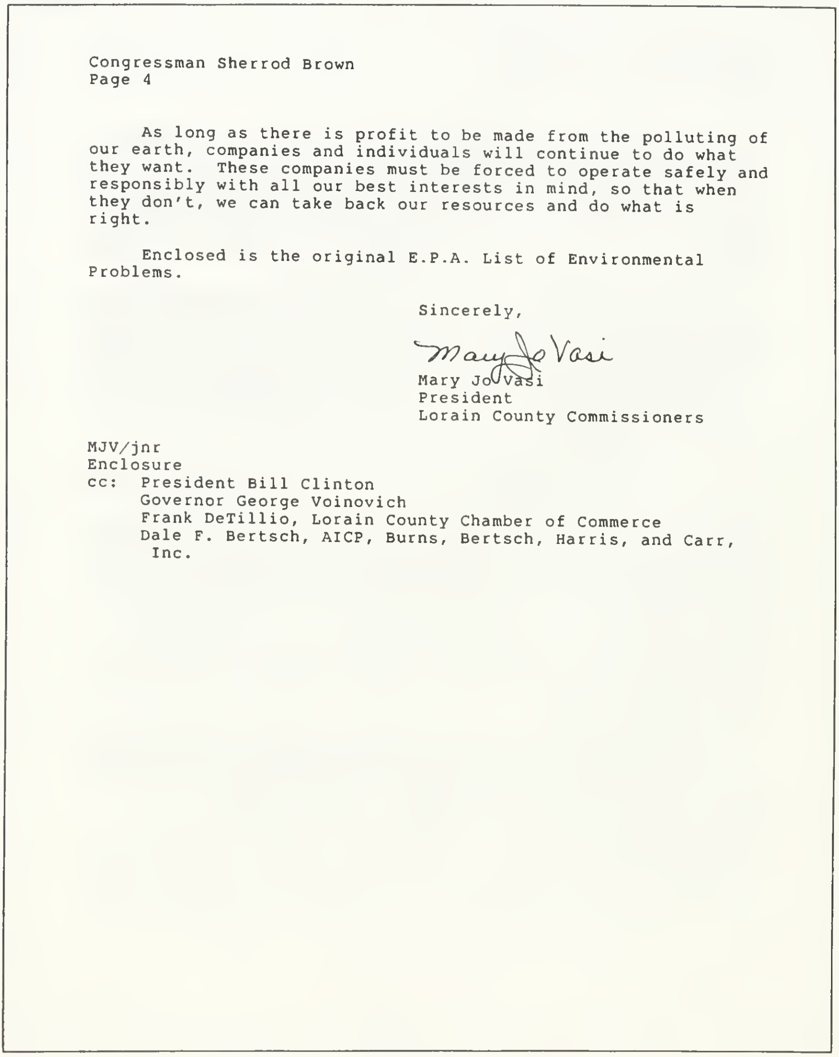
He contends that big business is primarily responsible for destroying the water we drink, the air we breathe and the food we eat. Having no cure for the world they destroy, only for the money they make in the process, millions and millions of gallons of oil are now destroying the ocean and the many forms of life it supports. Among these is plankton which supplies 60% to 90% of the earth's oxygen to support the entire marine ecosystem which forms the basis of our plant's food supply, but the plankton is dying.

Going to remote states or countries, anywhere on earth, and in doing a little research, he realized that these people broker toxic waste all over the world. They basically control the legislation, and in fact, they control the law. The law states that no company can be fined over $25,000 a day. If a company is making $10 million a day by dumping legal toxic waste into the ocean, it's only good business to continue doing this. They continue to influence the media so they can control our minds. If we speak out for ourselves, we're called conspiracy nuts or we're laughed at. We're being chemically and genetically damaged, and we don't even realize it.

Noxious, poisonous gases are emitted from our cars daily, and they're all cumulative poisons. They kill us slowly, even when we see no affect.

Asked what we can do, the speaker suggests the need for a responsible body of people that can actually represent us rather than big business. They would prohibit the introduction of anything into our environment that is not absolutely biodegradable or able to be chemically neutralized upon production.

County of Lorain



Congressman Sherrod Brown
Page 4

As long as there is profit to be made from the polluting of our earth, companies and individuals will continue to do what they want. These companies must be forced to operate safely and responsibly with all our best interests in mind, so that when they don't, we can take back our resources and do what is right.

Enclosed is the original E.P.A. List of Environmental Problems.

Sincerely,

Mary Jo Vasi

Mary Jo Vasi
President
Lorain County Commissioners

MJV/jnr
Enclosure
cc: President Bill Clinton
Governor George Voinovich
Frank DeTillio, Lorain County Chamber of Commerce
Dale F. Bertsch, AICP, Burns, Bertsch, Harris, and Carr, Inc.

Table III - Original EPA List of Environmental Problems

---

1 - Criteria air pollutants from mobile & stationary sources; acid deposition
2 - Hazardous/toxic air pollutants
3 - Other air pollutants, (e.g., flourides, total reduced sulfur)
4 - Radon (indoor pollution only)
5 - Indoor air pollution (other than radon)
6 - Radiation (other than radon)
7 - Substances suspected of depleting stratospheric ozone layer
8 - Carbon dioxide and global warming
9 - Direct point-source discharges to surface waters - industrial sources
10 - Indirect point-source discharges to surface waters - POTW's
11 - Non-point source discharges to surface water plus in-place toxics in sediments
12 - Contaminated sludge (includes municipal and scrubber sludges)
13 - Discharges to estuaries, coastal waters, and oceans from all sources
14 - Discharges to wetlands from all sources
15 - Drinking water at the tap (includes chemicals, lead from pipe, biological contaminants, radiation, etc)
16 - Active hazardous waste sites (includes hazardous waste tanks, inputs to groundwater and other media)
17 - Inactive hazardous waste sites (includes Superfund, inputs to groundwater and other media)
18 - Municipal non-hazardous waste sites (inputs to groundwater & other media)
19 - Industrial non-hazardous waste sites (includes utilities)
20 - Mining wastes (e.g., oil and gas extraction wastes)
21 - Accidental releases of toxics (all media)
22 - Accidental releases from oil spills
23 - Releases from storage tanks (includes product & petroleum tanks)
24 - Other groundwater contamination (septic tanks, road salt, injection wells)
25 - Pesticide residues on food eaten by humans or wildlife
26 - Application of pesticides (includes risk to pesticide workers as consumers who apply pesticides)
27 - Other pesticide risks (leaching, run-off, air deposition from spraying)
28 - New toxic chemicals
29 - Biotechnology (environmental releases of genetically altered organisms)
30 - Consumer product exposure
31 - Worker exposure to chemicals

Modified from: EPA Report "Unfinished Business: A Comparative Assessment of Environmental Problems" pages 10-11. (EPA, 1987a).

771 West 38th Street
Lorain, Ohio 44052
July 22, 1994

The Honorable Sherrod Brown
1407 Longworth House Office Building
Washington, DC 20515

Dear Congressman Brown:

While we applaud your Congressional inquiry into the high rate of breast cancer in Lorain County, we're very concerned that no attention is being paid to the closely related problem of prostate cancer which has an even higher death rate in our community than breast cancer. According to the National Cancer Institute, the death rate from prostate cancer in Lorain County is 31.55 per 100,000 population which is greater than any other county in Northeast Ohio and substantially higher than the National or Ohio averages! More of our friends, relatives and neighbors will die from prostate cancer this year than from breast cancer. As residents with families living here and as health care professionals who diagnose and treat prostate cancer patients, we find this extremely alarming and urge you to take steps to look into this dangerous situation.

There are a number of similarities between prostate and breast cancer and there may be a connection or common cause contributing to their abnormally high rates in Lorain County. Both tumors are more common in the senior years and the incidence of both increase as we age. Both occur more often when there is a positive family history of breast or prostate cancer. Both are thought to arise from long term exposure to hormones and both respond to hormonal therapy.

I personally treated a patient in Lorain with an exceedingly rare type of prostate tumor, called Phylloides Sarcoma. This is usually a tumor of the breast and not of the prostate. There are less than twenty reported cases in the world medical literature of Phylloides Sarcoma of the prostate. This again points out the possible connection between breast and prostate disease in Lorain County. Incidentally, an abnormally high rate of Germ Cell tumors has been reported in Lorain County, specifically in Avon Lake. These tumors are cancers of the ovaries and testes and are relatively rare.

When all of these facts are considered, they strongly suggest a common cause for these cancerous tumors. We urge you to remember this and include prostate cancer when you consider your actions and recommendations following the hearing.

A likely first step in investigating an abnormally high incidence of disease in a community like Lorain is to perform an epidemiological study. Lorain is well suited for such a study. We are an extremely diverse community ethnically which would tend to minimize ethnic background as a factor. Some of our industries, such as steel and chemicals, tend to produce relatively high levels of pollution which would disproportionately affect those who live in certain neighborhoods and who work in these plants. It is important to see whether patients with breast and prostate cancers live or work in the more heavily polluted areas or if there is some other common link between them.

Our brothers and sisters, mothers and fathers are dying of breast and prostate cancer at unacceptably high rates. There may be some environmental factors that would account for these high rates. We owe it to these people and their families to make every reasonable effort to identify such factors and eliminate them if possible. It would be unconscionable to exclude prostate cancer from this investigation.

Respectfully,

Stephen W. Leslie, MD FACS
Assistant Clinical Professor
Department of Urology, Medical College of Ohio

Prostate cancer rate high here

Saturday
June 2,
1994

By DUSTIN S. KLEIN
Morning Journal Writer

LORAIN — In addition to alarmingly high breast cancer death rates, Lorain County also exceeds state and national averages for prostate cancer deaths, according to the National Cancer Institute.

And the number of men killed by prostate cancer in Lorain County is nearly identical to the number of women who died from breast cancer, NCI reports show.

Some researchers believe hormones can trigger each disease.

Lorain County's breast cancer death rate was 24 percent higher than the national average 1987-1990, the most recent years for which NCI figures were available. For prostate cancer, Lorain County's death rate was 19 percent higher 1989-1992.

The county's death rate for both diseases also exceeds the state's average.

The high death rate for breast cancer in Lorain County and northeast Ohio has prompted Rep. Sherrod Brown, D-Lorain, to bring a House subcommittee to Lorain for a hearing. The hearing will take place Aug. 1 at St. Joseph Hospital and Health Center in Lorain.

A hormonal link between breast cancer and prostate cancer may account for similarities.

Brown will attempt to determine the extent of the problem and possible solutions.

Cancer researchers say a hormonal link between breast cancer and prostate cancer may account for similarities between the two diseases, including how they spread and their growth time.

Please see **CANCER**, page A8

From the front page

Hormone manipulation treatment is common between several forms of the two cancers, said Kathy Grueschow, director of cancer services at St. Joseph Hospital and Health Center.

Ms. Grueschow said some forms of breast cancer are hormone-activated and are dependent on the body hormone estrogen for their growth. Many prostate cancer cases grow based on testosterone hormone releases in the body, she said.

"There are some similarities between the two which are connected to hormones in the body," said Nahida Gorden, a biostatistician for the University Hospitals Cancer Center in Cleveland.

Ms. Gorden said the chance of developing prostate cancer increases with age in men, a problem that also occurs with women over 40 and breast cancer.

Both diseases also can metastasize, or spread, to the bone and other parts.

Breast cancer can also spread to the liver, brain and lungs if it is not identified early, she said.

And both breast and prostate cancer can grow slowly without detection, sometimes up to 20 years, said Dr. Forrest Pommerenke, of the early detection branch of the National Cancer Institute.

Dr. Pommerenke said if the cancers are not aggressively attacking the body, the tumors can grow slowly and unnoticed.

However, one major difference between the two diseases is that men can often live with prostate cancer for years without getting treatment, while women must treat breast cancer before it become fatal, said Georgette Haydu, cancer research coordinator for the Ohio Department of Health.

Mrs. Haydu said depending on whether the prostate cancer is spreading, doctors often take a wait-and-see attitude on treatment because the disease is not always fatal.

But that's not the case with breast cancer, and Mrs. Haydu said that's the reason for a pilot program her department is undertaking in Cleveland to get lower-income women to get breast exams.

A lot of lower-income women neglect getting mammograms because they don't want to know if they've got breast cancer, she said.

But the pilot program, being completed through a grant by the NCI, hopes to raise awareness of breast cancer among that group, and if successful will be expanded into Lorain County and throughout Ohio, Mrs. Haydu said.

NCI figures show that between 1987 and 1990, an average of 81 women died each year from breast cancer in Lorain County. That's based on a death rate of 30 per 100,000.

However, 13 fewer women would have died each year had the county's breast cancer de[illegible] rate been in line with the natio[illegible] average of 25.20 per 100,000.

As for prostate cancer, NCI [illegible]ures show an average 85.5 men died each year from the disease between 1989 and 1992 in Lorain County. The figure is based on a death rate of 31.55 per 100,000 in the county.

Some 17 fewer men would have died each year had Lorain County's death rate been the same as the national average of 25.30, according to NCI reports.

CANCER DEATHS

Breast cancer and prostate cancer have similar death rates. Chart shows deaths each year per 100,000 people.

	prostate	breast
LORAIN COUNTY	31.55	30.00
ERIE COUNTY	21.73	25.50
HURON COUNTY	22.45	35.90
LAKE COUNTY	26.28	30.20
CUYAHOGA COUNTY	31.23	33.50
OHIO AVERAGE	27.45	29.90
U.S. AVERAGE	25.30	25.20

Prostate cancer death rates cover data collected from 1989 through 1992, while breast cancer death rates cover the period from 1987 to 1990, the most recent data collected by the National Cancer Institute.

SIMILAR DISEASES

Cancer researchers say there are several similarities between breast and prostate cancer, which lead them to believe there is some link between the two.

- **SAME TRIGGER:** Both diseases are suspected to be activated by hormones. Estrogen drives growth of some breast cancer tumors while testosterone pushes growth of some prostate cancer cases.
- **ATTACKS BONE:** Left untreated, aggressive cases of breast and prostate cancer mestastasize, or spread, to the bone.
- **LONGEVITY:** Breast and prostate tumors can grow undetected for up to 20 years in some cases before being detected.
- **LOCAL DEATHS:** Lorain County has shown high death rates which are similar from breast and prostate cancer since the late 1980s.

SHOULD YOU FILE
BANKRUPTCY?
CALL 323-4800
Carl G. Hitcman
Attorney at Law
320 Broad St.
Elyria

Prostate cancer, too

A subcommittee of the U.S. House of Representatives has confirmed that it will hold a hearing in Lorain Aug. 1 on the concern over a high rate of breast cancer deaths in Lorain County.

The attention to this grave threat to women's health is appreciated. We urge the committee to add to the hearing agenda consideration of a related question of similar consequence to men — prostate cancer.

The hearing of the House subcommittee on Health and the Environment, chaired by Rep. Henry Waxman, D.-Calif., was scheduled at the urging of Rep. Sherrod Brown, D-Lorain, who is a member of the committee. Brown said he was concerned about reports from the National Cancer Institute that showed Lorain County's rate of deaths from breast cancer is higher than the state and national averages.

Further information from NCI shows that the death rate for Lorain County men from prostate cancer is similarly above average. According to the most recent data on each type, there were 30 deaths per year per 100,000 people from breast cancer, 31.55 from prostate cancer.

The significance of this is these cancers are similar. Both are thought to be triggered by hormones. Estrogen drives growth of some breast cancer tumors while testosterone pushes growth of some prostate cancer cases.

Left untreated, aggressive cases of both types of cancer will spread to the bone. Tumors from both can grow slowly, undetected, for up to 20 years in some cases.

Rep. Brown said the purpose of the hearing in Lorain will be to determine the extent of the problem of breast cancer and hear expert advice on possible solutions. The event may also give impetus to a proposal for more research at the local level.

We have the impression that women are more vocal than men in campaigning for more research and awareness on these cancer threats. This may be because of a perception that breast cancer is more dangerous than prostate cancer. Breast cancer that is ignored is usually fatal, while men often live for years with untreated prostate cancer.

The NCI data on death rates seems to suggest, however, that men and women in Lorain County have equal reason to fear these similar diseases. That information should prompt the committee to take up both at the August hearing.

UROLOGY TIMES
VOL. 22, NO. 7 • The Leading Newsmagazine for Urologists • JULY 1994

Prostate Ca Deaths Higher than Thought

Nearly two-thirds die with watchful waiting or endocrine tx

AUA CONVENTION REPORT

San Francisco—A man with prostate cancer who survives 10 years, especially an older man, is likely to die of something else, right?

Wrong, according to a Swedish study that surprised many American urologists here at AUA's 89th Annual Meeting.

Among its findings were that nearly two-thirds of men with prostate cancer managed without intent to cure—watchful waiting or endocrine therapy only—will die of prostate cancer itself. That includes about 50% of men with no distant metastases at diagnosis and 62% of them if they survive more than 10 years. In addition, a man treated this way has to be at least 75 years old before his risk of dying of prostate cancer itself drops to less than 50%.

What made these data from Göteborg, Sweden, on disease-specific survival so compelling was the study's very long follow-up—as much as 26 years—and solid information on the cause of death from careful assessment of medical records—not just death certificates.

Working in Sweden gave Gunnar Aus, MD, and his colleagues John Hugosson, MD, and Lars Norlén, MD, at the University of Göteborg an opportunity to study prostate cancer survival that few others have, Dr. Aus told Urology Times. "Scandinavian studies are generally population-based. All patients with a diagnosis in one geographic area are included. People from Göteborg, for example, don't go to Stockholm for an examination. They go to the hospital in their community, so their records are there. And everybody in Sweden has a personal identification number that allows us to follow them from birth to death, so you can find data on every patient."

In addition, prostate cancer used to be managed with watchful waiting or endocrine therapy alone in Sweden, which differs from the way it is managed in the United States.

That allowed Dr. Aus and his colleagues to look at the records of an unselected population of 514 patients who had prostate cancer managed without intent to cure and who died during the years 1988 to 1990 in Göteborg. Overall, 62% of patients died of prostate cancer, whereas 38% died of unrelated causes.

More Die of Prostate Cancer

Dr. Aus and his colleagues looked at the influence of cancer grade and stage on survival among the 301 patients (59%) who had no metastases at diagnosis. Ultimately, 50% of the patients without metastases at diagnosis died of prostate cancer.

Patients with early T stages seemingly did well. Among those with stage T1a disease at diagnosis, no patient died of prostate cancer before 19 years of follow-up, and only a few ultimately died of prostate cancer. Patients with T2a disease had a high 10-year disease-specific survival of 79% and a median disease-specific survival of 15 years—about what would have been expected from previously published studies with this much follow-up. However, longer-term follow-up showed that, ultimately, half (52%) of patients with T2a disease at diagnosis died of prostate cancer.

About 50% of patients with stage T1b or T2b-T3 tumors died of prostate cancer, with a much shorter median survival time of 8 years. Patients with fixed tumors did poorly.

Data on cancer grade among the patients with no metastases at diagnosis showed a 10-year disease-specific survival of 70% for grade 1, 47% for grade 2, and 19% for grade 3.

Among all patients who survived for more than 10 years with noncurative management—the ones likely to have localized disease and who might benefit from treatment, Dr. Aus noted—63% died of prostate cancer.

Studies at Odds?

To some attendees, these results seemed at odds with those from Dr. Aus's Swedish colleague, Jan-Erik Johansson, whose landmark studies (*JAMA* 1992, 267:2191; *Urology* 1994, 43:138) have provided a foundation for the argument for watchful waiting, especially for older patients. Dr. Johansson's study noted a decline in deaths because of prostate cancer by 10 years of follow-up, and he stated that that trend would continue; that is, by 10 years, most prostate cancer deaths have taken place, and patients living longer are likely to die of something else.

"Our data are practically the same. We show the same outcome group-for-group up to 10 years," Dr. Aus told UT. "At that point, prostate cancer survival is excellent because there is so much comorbidity in elderly men."

But the difference comes with longer follow-up, he pointed out.

"If one continues to look at the patient after 10 years, that's when the mortality from prostate cancer comes." Some patients in the study were followed as long as 25 years.

Not by Age Alone

The patients likely to live more than 10 years are the ones most likely to benefit from therapy intended to cure. How to judge which patients those are is a challenge. "If I had a good way to do that, I would have the Nobel prize," Dr. Aus quipped to UT.

But age alone isn't the determining factor. How the risk of dying of prostate cancer correlated with age held one of the largest surprises for Dr. Aus's American colleagues. Yes, their risk of dying of prostate cancer that was not initially metastasizing did decline with age, but analysis showed a man had to be older than age 75 years before the risk dropped to less than 50%.

Implications for Clinicians

Ralph W. deVere White, MD, who moderated this lively session, put these data in perspective for American urologists, 80 to 90% of whose prostate cancer patients have grade 2 or grade 3 cancer.

"A 65-year-old walks in to you next week, and he is in good health, and you say he has grade 2 cancer, what is his chance of dying of prostate cancer in the next 10 years if he goes on this kind of treatment?"

"That would be in the range of 30%," Dr. Aus replied.

"And his chance if he lives beyond 10 years of dying of prostate cancer?"

"It would go up to 65%—about."

Echoing the thoughts of many urologists in the room, Dr. deVere White concluded, "Certainly, it would be a very sobering thought if one wanted to sit around and defer treatment with a 65% chance you were going to die of prostate cancer."

But Dr. Aus was somewhat cautious about the implications of his study for treatment. After all, he pointed out, patients in this study were diagnosed before the era of prostate-specific antigen (PSA) testing. "That means you can't take these results and apply them to a population diagnosed by PSA screening because of the lead-time bias. Patients diagnosed 5 years earlier than they would have been otherwise survive 5 years more."

But when he tries to judge a patient's likelihood of surviving more than 10 years, he considers the patient's condition, not just his age.

"There was, in fact, one patient who survived more than 10 years who was over 84 years of age at the time of his diagnosis, and he later died of prostate cancer. So, you can't use just age as a cutoff. You can't say that at age 70 years and beyond nobody needs curative treatment. You have to look at the general health of the person who is sitting in front of you," he concluded.

—**Penny Allen**
Managing Editor

LETTER TO *THE NEW YORK TIMES*

MIDDLE-AGED PROSTATE PATIENTS CAN'T RISK WATCHFUL WAITING

The following letter from the 1993-1994 AUA President appeared in the Feb. 14 issue of The New York Times.

To the Editor:

A study published in the Jan. 27 issue of *The New England Journal of Medicine* examined the role of watchful waiting as a treatment option for prostate cancer. It received widespread news coverage, for which the American Urological Association offers some follow-up clarification.

Prostate cancer is a slow-growing tumor in older men. It is often diagnosed in men with life expectancies of less than 10 years and other significant health problems. In these cases, watchful waiting is appropriate, as the journal article states.

However, the same study showed that 13% of men with early and intermediate grades of prostate cancer died within 10 years of diagnosis. In addition, cancer spread had occurred in 19% of tumors that had been diagnosed early and 42% of intermediate grade cancers. Men with the most serious malignancies at diagnosis fared especially poorly; 68% died of cancer, and 74% suffered a spread of malignancy within 10 years.

Once the malignancy spreads, successful treatment becomes extremely difficult.

When prostate cancer is diagnosed while it is still confined to the prostate gland, the cure rate with surgery is high. But once the malignancy has spread, successful treatment becomes extremely difficult. Therefore, watchful waiting may not be a prudent course of action for many middle-aged men diagnosed with prostate cancer. For them delaying more aggressive therapy may result in missing an opportunity for cure and risking the cancer's spread.

The data in *The New England Journal of Medicine* article were collected before development of the prostate specific antigen test to help physicians diagnose prostate cancer. This blood test is helping physicians and patients determine the most prudent course of treatment. We strongly advise men who are diagnosed with prostate cancer to discuss their treatment options carefully with their physicians and make sure they get all the facts about the risks and benefits of both watchful waiting and aggressive surgical therapy.

Abraham T.K. Cockett, M.D.
President, American Urological
Association

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Statement to the House Energy and Commerce Subcommittee on Health and Environment

Field Hearing on Breast Cancer and the Environment in NE Ohio

Lorraine, Ohio *August 1, 1994*

Remarks submitted by
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My research in environmental health has centered on quantitating exposures of humans to chemicals that occur in the environment, including air pollutants, pesticides, lead, polycyclic aromatic hydrocarbons, solvents, and halogenated hydrocarbons. I have participated in numerous studies of persons exposed in the normal environment or occupationally to organochlorine pesticides and PCBs (polychlorinated biphenyls). Many of these chemicals are known to be estrogenic and carcinogenic. Our department has conducted numerous epidemiologic studies dealing with environmental exposures to such halogenated hydrocarbons within our Environmental Health Sciences Center that is funded by the National Institute of Environmental Health Sciences (NIEHS). oUR research on breast cancer is supported by NIEHS and the National Cancer Institute (NCI).

My research interests during the past few years have been focussed on the relation of environmental exposures to breast cancer. Our published reports have been performed in collaboration with colleagues at Hartford Hospital (Dr. Frank Falck and others),[1] at the New York University Institute of Environmental Medicine (Dr. Paolo Toniolo and others),[2] and at the Kaiser Research Institute in California (Dr. Nancy Krieger and others).[3]

Unfortunately, there is not a great deal of information to guide us about exposure to chemicals in the environment and risk of breast cancer. This is suprising, given the recognized contribution of unkown environmental risk factors to breast cancer causation. It has been suggested that the environment accounts for much of the risk, since relatively little is explained by genetics, age and reproductive history. This environmental concept encompasses lifestyle factors such as diet as well as carcinogenic agents such as radiation. However, as I have suggested, environmental chemicals *per se* have not been widely accepted as risk factors for breast cancer.

A number of recent investigations have assessed exposure to persistent organochlorines in relation to breast cancer risk. These chemicals include pesticides—DDT, chlordane, hexachlorobenzene, benzene hexachloride (BHC a.k.a. lindane) -- as well as halogenated biphenyls (polychlorinated biphenyls or PCBs and polybrominated biphenyls or PBBs). They are biologically persistent and carcinogenic in animals; for these reasons and for their harmful reproductive effects in wildlife, they were banned in the 1970's in the U.S. Their long persistence in the body, however, and their continuing presence in the environment makes it possible for us to detect them even now in American men and women.

One potential mechanism that may explain the biological effects of environmental chemicals of this kind is their potential estrogenicity. In other words, many of these substances are able to mimic reproductive hormones. Rachel Carson documented hormonal disruption by DDT in wildlife and warned us that excessive human exposure was occurring in the 1950s. Recently, environmental contamination has been suggested as a cause for continuing endocrine dysfunction in both male and female birds and amphibians.[4] An important human observation that led to our research was made by Walter Rogan and his colleagues at NIEHS in the 1980s. They found that women with higher levels of DDE reported shorter duration of lactation, suggesting a hormonal effect of DDT.[5] (DDE is the major residue of DDT in the environment, and it is usually found in humans at higher levels and more often than any other organochlorine.)

There have been four recent studies case-control studies linking environmental organochlorine exposures to breast cancer risk. Two involved our laboratory at Mount Sinai. The first was Frank Falck's study, published in 1992, showing approximately 50% higher levels among 20 breast cancer cases of DDE [bis(4-chlorophenyl)-1,1-dichloroethene], DDT [bis(4-chlorophenyl)-1,1,1-trichloroethane], and higher chlorinated PCBs, compared with 20 controls.[1] There was approximately 1% increased risk for every 10 parts per billion of these chemicals in adipose tissue.

The second study, published in April 1993, was a collaboration between two NIEHS Environmental Health Sciences Centers—Mount Sinai School of Medicine and New York University Medical Center.[2] Again, levels of DDE and PCBs were higher among breast cancer cases than among carefully matched controls, but only for DDE were the differences statistically significant. Women with highest levels of DDE (the upper 10%) had about four-fold increased risk compared with women whose levels were in the lowest 10%. There was approximately 9% increased risk for every one part per billion of DDE in blood serum. (The usual concentration of chemicals in adipose tissue is approximately 200 times that in blood serum.) The relative risks reported in these studies are in the same range as those estimated from the animal data.[6] [7]

Similar risks for breast cancer were found among Finnish women who had elevated levels of *beta*-hexachlorocyclohexane, a lindane-related residue.[8] More recently, Canadian researchers reported higher DDE levels among patients with estrogen receptor-positive breast cancer than among estrogen receptor-negative patients or controls.[9]

A fifth study published in April 1994 looked at Caucasian, African-American, and Asian women (50 cases and controls in each ethnic group). Blood had been collected in the late 1960s, prior to cancer diagnosis. This study also used our laboratory at Mount Sinai. Marked differences in exposure were observed with respect to ethnicity, but the differences of DDE and PCBs between cases and controls were not statistically significant. However, among African-American and Caucasian women, the trends of the adjusted relative risks with respect to DDE levels were consistent with earlier data, although still not statistically significant. The upper confidence intervals included the risk ratios observed in earlier studies.

The studies described have used well-defined exposure measurements, since an internal dose was obtained for each woman in these reports. There are also a few studies that employed an ecological design, which attempt to demonstrate a link between breast cancer and environmental exposures by examining rates of breast cancer in a geographic area where unusual contamination can be identified. For example, elevated rates of breast cancer and other cancer were observed at EPA hazardous waste sites where significant water pollution was also found.[10] More recently, Melius and colleagues at the New York State Department of Health reported elevated risk of breast cancer on Long Island associated with residence nearby potentially hazardous chemical facilities.[11] These reports can be followed up by investigations that attempt to more precisely measure exposure to environmental agents.

Much remains to be done to confirm the findings linking environmental exposures to breast cancer and to clarify the underlying mechanisms.[12] The potential for organochlorines like DDT to act like estrogenic suggests that other diseases should be investigated, including reproduction, neurologic function, and immunologic competence. In addition to breast cancer, other cancers associated with hormones may be affected by environmental exposures, including cancers of the female reproductive tract (uterine, ovarian) as well as prostate and testicular cancer.

It is also important for us to determine whether there are other chemical exposures that may be related to breast cancer risk. There are numerous potentially estrogenic chemicals now in commerce, other than DDT and PCBs, such as atrazine and methoxychlor.[4] Methoxychlor is highly estrogenic, but it is not as persistent as DDT. In fact, most chemicals used as pesticides today are not persistent in the environment, and therefore we are unable to quantitate them in the body long after exposure occurs. This makes it difficult to make associations with cancer or with other chronic diseases in epidemiologic studies.

When we cannot make good exposure estimates, we must rely on animal experiments to guide our policy decisions for protection of public health. Potential hormonal effects of new chemicals introduced into commerce could be a harbinger of possible long-term health effects. It is very important to support these lines of research. A recent example of this was the withdrawal by the EPA of vinclozolin on the basis of animal tests that showed androgenic effects in experimental models.

Because so little is known about breast cancer causation, we cannot ignore the possibility that chemical exposures may play a role in this disease. Rates of breast cancer occurrence in the U.S. have steadily risen since 1940. During that same period, levels of pesticide and PCB residues in human adipose tissue in the U.S.have shown parallel increase, following their introduction into commerce around the time of World War II. Since then, despite much research on the question, only three factors have been generally agreed to be strongly linked to breast cancer: age, country of birth and family history. These factors are not readily amenable to change.

The great promise that environmental research holds is that human exposures to harmful chemicals can be avoided, and therefore diseases associated with such chemicals may then be prevented. Therefore the efforts of this committee should continue to support research into the environmental causes of breast cancer and into identifying chemicals with potential for hormone disruption and carcinogenesis whose hazardous effects can be minimized.

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July 20, 1994

University of Pittsburgh
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The Hon. Sherrod Brown
Energy and Commerce Subcommittee on
Health and the Environment
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Dear Congressman Brown:

At the request of one of your constituents, I am sending you a number of recently published papers relating to the subject of your upcoming hearings on breast cancer scheduled to be held on August 1, 1994 in Elyria, Ohio.

The significance of the enclosed papers is that they present overwhelming evidence that the biological effect of radioactive fission products released into the air, the water and the human diet by nuclear tests and nuclear reactors is hundreds to thousands of times greater than short exposures to external sources of radiation on which present radiation standards developed during the Cold War are based, particularly so for the case of breast cancer.

The reason is that for protracted, chronic exposures to radiation such as produced by strontium-90 in bone, the dominant biological effect is due to damage to membranes of the immune system cells in the bone marrow which protect the body against the proliferation of cancer cells, viruses and bacteria. For short, intense external exposures such as from the flash of an atomic bomb or a medical X-ray, the dominant mechanism is direct damage to the DNA in the center of a cell that frequently results in a mutation that produces a cancer cell. Whereas the direct damage to a DNA molecule that produces a new cancer cell requires about the same high dose regardless of whether it is received in a second or in a year, the indirect damage to cell membranes by free radicals or short-lived toxic molecules such as that of oxygen becomes increasingly more efficient as the dose is spread out in time. As a result of this so-called Petkau effect, chronic exposures from radioactivity in the diet and drinking water can be thousands of times more effective in producing cancer, low birthweight, immune deficiency, illness and death than expected on the basis of nearly a century of medical experience or the follow-up of the A-bomb survivors.

Moreover, the relation between radiation dose and biological effect is no longer linear as had been assumed on the basis of high dose external exposures, but instead rises sharply at very small doses and then levels off at high doses. As a result, an extrapolation from high to low doses used by standard setting agencies that assumes a straight-line relationship grossly underestimates the effect of protracted internal exposures from ingested fission products that do their damage slowly over periods of months to years.

This explains why these recent studies and the more than two dozen earlier studies cited in them that found increased infant mortality, leukemia and cancer around nuclear facilities could be disregarded by government agencies and radiation control organizations during the Cold War years on the grounds that the doses were far too small to account for the observed effects. But now that decades of exposures of very large populations around nuclear facilities involving millions of individuals exposed to officially documented amounts of fission products in the diet show a concave downward curvilinear dose-response curve, one can no longer disregard the studies that show serious effects at extremely small doses.

PRESBYTERIAN-UNIVERSITY HOSPITAL, RC 406 A-STEM, PITTSBURGH,PA 15261

In addition to the recently published papers, I am also sending you the following material:

1) Testimony on the breast cancer epidemic presented before the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Operations held on October 30, 1993 in Long Island, New York.

2) A report by Dr. J. M. Gould, a statistician and former member of the EPA' s Science Advisory Committee, on how a 1990 study of cancer rates by the National Cancer Institute near nuclear facilities requested by Congress was designed so as to minimize any possible excess cancer mortality near nuclear facilities, and which misrepresented the actual data that showed a highly statistically significant increase relative to the U.S. as a whole.

3) A summary of a forthcoming paper on breast cancer around the Oak Ridge National Laboratory in Tennessee by Dr. J. M. Gould which indicates that the rise in breast cancer mortality for 103 counties within a radius of some 100 miles of this nuclear facility between the early 1950s and the late 1980s was 19.6% compared with 0.7% for the nation, or 28 times greater than for the U.S. as a whole. This data on breast cancer mortality fully supports the earlier studies by Mangano on total cancer rates near Oak Ridge and the nationwide study by Gould and myself that recently appeared in the International Journal of Health Services published by Dr. Vicente Navarro at the Johns Hopkins University School of Public Health showing a close association of breast cancer rates with the reported regional releases from nuclear reactors .

4) A news release announcing a press conference on the breast cancer epidemic around the Oak Ridge National Laboratory, July 22, 1994.

These papers and reports indicate that nuclear releases from nuclear testing, routine reactor releases and major accidents appear to be the single greatest environmental factor responsible for the recent rises in breast and other types of cancer, often acting synergistically with pesticides and other chemicals. These releases now appear to have produced thousands of times greater health, economic and social damage than has been widely assumed by the public kept uaware of these findings by the Department of Energy and the Department of Defense for decades as a result of Cold War secrecy. It also means that the recent sharp rises in cancer rates not related to smoking such as breast cancer, the resurgence of low birthweight, and the unprecedented increase in the mortality of young people in areas close to nuclear reactors or reprocessing facilities described in the accompanying studies can only be halted and reduced if radioactive emissions are cut by a hundred to a thousand fold, and the reactors are replaced by more benign sources of energy as rapidly as possible. Only if Congress demands that this be done can we hope to control the enormous rise in health and welfare costs now threatening the very future of our nation.

Ernest J. Sternglass

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THE RELATIONSHIP OF IONIZING RADIATION AND BREAST CANCER

August 1, 1994 Congressional Hearing

The incidence of breast cancer is a veritable epidemic, having more than doubled since 1960 from one in twenty to one in eight today! There are many theories regarding causation and possible prevention of breast cancer including heredity, age of menstruation, childbirth, breastfeeding, onset of menopause, diet (especially fat intake), alcohol consumption, cigarette smoking, and exposure to environmental pollutants including chemicals like PCB's, DDT, dioxins and organochlorines which mimic natural hormones including estrogen, a risk factor associated with breast cancer.

Ionizing radiation, which results from splitting atoms in nuclear weapons and nuclear power plants, breaks molecular bonds and can damage cells and internal organs. The fact that ionizing radiation causes cancer and is especially damaging to sensitive breast tissue has long been known. "Radiation has long been known to induce breast cancer in women, as first observed in a large scale study of women exposed to a series of fluoroscopic X-ray examinations in the course of treatment for tuberculosis."(1)

Medical and scientific research abounds on the carcinogenic properties of ionizing radiation even at very low doses. Some of the most recent research has been submitted to this Congressional committee. (See also attached biographical information)

Two world renowned experts who helped develop the atom bomb, Dr. Karl Z. Morgan, Ph.D. and Dr. John W. Gofman, M.D., Ph.D. have said respectively, "Low levels of radiation not only cause cancer and genetic defects, but may even be more harmful than higher doses per unit exposure" (2) and "There is no safe dose or dose rate of ionizing radiation with respect to the induction of human cancer." (3)

A 1979 National Academy of Sciences report said radiation exposure can initiate genetic defects, virtually every type of cancer, heart disease , aplastic anemia, cataracts, and weakened immunity. (4)

Recent studies of Japanese atomic bomb survivors show conclusively that low dose radiation is more harmful and causes more cancer than previously projected. (5)

A December 1988 United Nations report concluded that the risk from radiation was 3 times higher than previously thought. (6)

In 1990, the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR V) reported that the cancer causing effects of radiation are 3 to 12 times higher than previously believed, depending on the type of cancer being considered.

Research published in the March 20, 1990 *Journal of the American Medical Association (JAMA)* based on a long-term study of over 8,000 workers at the Oak Ridge National Laboratory, concluded a 10 times greater cancer risk from radiation exposure than was previously estimated and a large scale, long-term study of British radiation workers published in the January 25, 1992 *British Medical Journal* showed similar results.

Multiple epidemiological studies now suggest that radioactive releases from nuclear power plants significantly increase the incidence of breast cancer in women who live within 15-30 miles of the reactors.

In recent Congressional testimony, books, and published research, Dr. Ernest J. Sternglass, Ph.D. and his colleague Dr. Jay Gould, Ph.D. have demonstrated persuasive evidence linking "the rise in breast cancer to routine radioactive releases from nuclear reactors acting synergistically with chemicals released into our air and water." (7)

Drs. Sternglass and Gould have documented among other things that the rise of breast cancer

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in communities within 15 miles of the Brookhaven National Laboratory, a 40 year old nuclear complex in Suffolk County, NY is 11.1% higher than for the rest of the Suffolk county (the likelihood of this occurring by pure chance is less than one in 10,000.)

"It appears that the high incidence of breast cancer found by the NY State Health Department in communities located within about 15 miles of Brookhaven National Laboratory is related primarily to the action of radioactive releases from this facility during the past four decades contaminating the air, the agricultural products and the drinking water."

A recently published analysis near Oak Ridge, TN, site of one of the oldest U.S. nuclear facilities, also suggests increased breast cancer mortality compared to counties less exposed to radioactive emissions from the plant. "According to National Cancer Institute studies, age-adjusted breast cancer mortality rates of white women have increased in counties (closest to) Oakridge by 19.6 percent since 1950, compared to a 0.7 percent increase for the U.S. as a whole." (The probability of this occurring by chance is less than one in 10 million.)

In a recent letter to Congressman Sherrod Brown, Dr. John Gofman summarized his current comprehensive research on the subject of "Breast Cancer Causation" which will be published in the next few months. "It is a matter of proven record that ionizing radiation is DEFINITELY A CAUSE OF BREAST CANCER IN WOMEN...Therefore, I conclude that a very large share of breast cancer is caused by ionizing radiation...And I should point out that accelerators of breast cancer can act together with (in synergy with) ionizing radiation. Given the status of these calculations, it is reasonable to recommend that all sources of unnecessary ionizing radiation, FROM BIRTH ON, should be drastically restricted - if anyone is serious about starting the prevention effort with respect to breast cancer." (emphasis is Dr. Gofman's.)

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July 22, 1994

Subject: Congressional hearings on the high breast cancer incidence in Northeast Ohio, held August 1, 1994.
Please include the following information in the record.

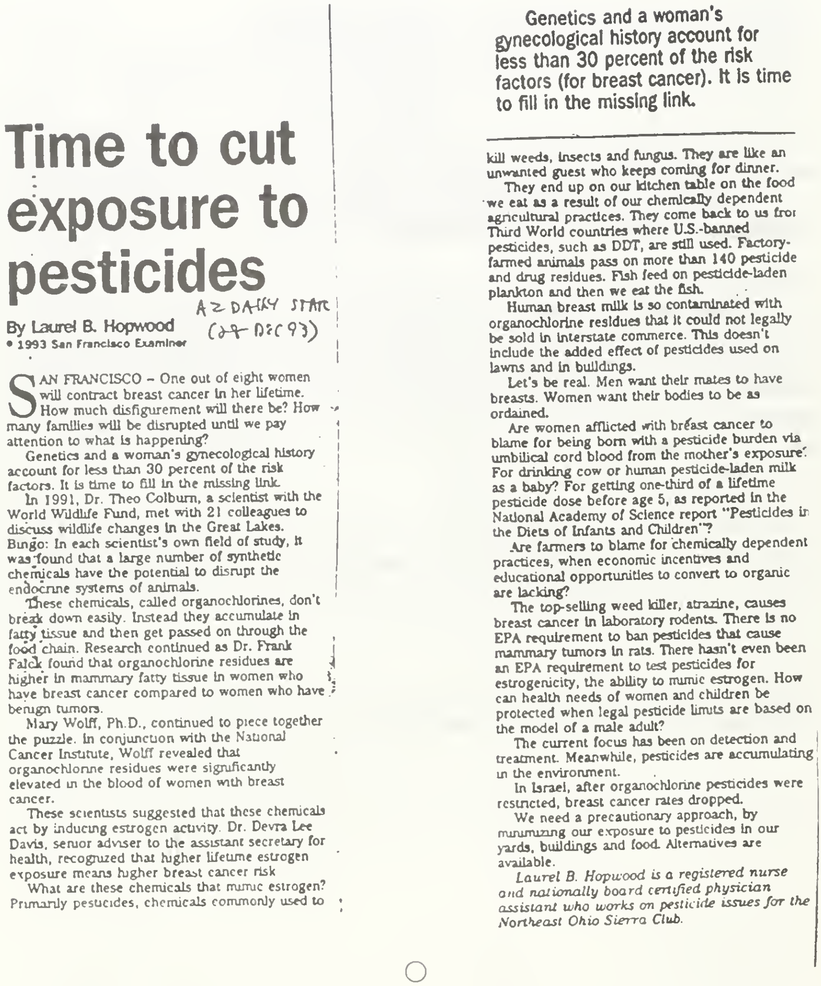
To Mr. Sherrod Brown;

In the past few years, scientific studies have been linking breast cancer with environmental factors, such as organochlorines (persistent synthetic chemicals that accumulate in fatty tissue and pass throughout the food chain). A large source of organochlorines is pesticides (chemicals used to kill weeds, insects and fungus.) It seems prudent to focus on a preventative approach, such as significantly reducing pesticides used in agriculture and lawns/golf courses.

Enclosed is an op-ed written by myself that summarizes key issues concerning the food chain link and information taken from the U.S. General Accounting Office report *Pesticides: Issues Concerning Pesticides Used in the Great Lakes Watershed* (GAO/RCED-93-128).

Laurel Hopwood

Laurel Hopwood, Registered Nurse and Physician Assistant
Northeast Ohio Sierra Club Pesticide Chair



Time to cut exposure to pesticides

AZ DAILY STAR (28 DEC 93)

By Laurel B. Hopwood

• 1993 San Francisco Examiner

Genetics and a woman's gynecological history account for less than 30 percent of the risk factors (for breast cancer). It is time to fill in the missing link.

SAN FRANCISCO – One out of eight women will contract breast cancer in her lifetime. How much disfigurement will there be? How many families will be disrupted until we pay attention to what is happening?

Genetics and a woman's gynecological history account for less than 30 percent of the risk factors. It is time to fill in the missing link.

In 1991, Dr. Theo Colburn, a scientist with the World Wildlife Fund, met with 21 colleagues to discuss wildlife changes in the Great Lakes. Bingo: In each scientist's own field of study, it was found that a large number of synthetic chemicals have the potential to disrupt the endocrine systems of animals.

These chemicals, called organochlorines, don't break down easily. Instead they accumulate in fatty tissue and then get passed on through the food chain. Research continued as Dr. Frank Falck found that organochlorine residues are higher in mammary fatty tissue in women who have breast cancer compared to women who have benign tumors.

Mary Wolff, Ph.D., continued to piece together the puzzle. In conjunction with the National Cancer Institute, Wolff revealed that organochlorine residues were significantly elevated in the blood of women with breast cancer.

These scientists suggested that these chemicals act by inducing estrogen activity. Dr. Devra Lee Davis, senior adviser to the assistant secretary for health, recognized that higher lifetime estrogen exposure means higher breast cancer risk

What are these chemicals that mimic estrogen? Primarily pesticides, chemicals commonly used to kill weeds, insects and fungus. They are like an unwanted guest who keeps coming for dinner.

They end up on our kitchen table on the food we eat as a result of our chemically dependent agricultural practices. They come back to us fro[m] Third World countries where U.S.-banned pesticides, such as DDT, are still used. Factory-farmed animals pass on more than 140 pesticide and drug residues. Fish feed on pesticide-laden plankton and then we eat the fish.

Human breast milk is so contaminated with organochlorine residues that it could not legally be sold in interstate commerce. This doesn't include the added effect of pesticides used on lawns and in buildings.

Let's be real. Men want their mates to have breasts. Women want their bodies to be as ordained.

Are women afflicted with breast cancer to blame for being born with a pesticide burden via umbilical cord blood from the mother's exposure? For drinking cow or human pesticide-laden milk as a baby? For getting one-third of a lifetime pesticide dose before age 5, as reported in the National Academy of Science report "Pesticides in the Diets of Infants and Children"?

Are farmers to blame for chemically dependent practices, when economic incentives and educational opportunities to convert to organic are lacking?

The top-selling weed killer, atrazine, causes breast cancer in laboratory rodents. There is no EPA requirement to ban pesticides that cause mammary tumors in rats. There hasn't even been an EPA requirement to test pesticides for estrogenicity, the ability to mimic estrogen. How can health needs of women and children be protected when legal pesticide limits are based on the model of a male adult?

The current focus has been on detection and treatment. Meanwhile, pesticides are accumulating in the environment.

In Israel, after organochlorine pesticides were restricted, breast cancer rates dropped.

We need a precautionary approach, by minimizing our exposure to pesticides in our yards, buildings and food. Alternatives are available.

Laurel B. Hopwood is a registered nurse and nationally board certified physician assistant who works on pesticide issues for the Northeast Ohio Sierra Club.

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